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The Committee recommends that further work be conducted before the risk assessment methodologies are used to develop numerical criteria. Major shortcomings include various unexplained technical omissions and overly conservative and unrealistic risk assessment assumptions, including a sole focus on "maximum exposed individual" risks, the fairlure to consider a range of risks, and the absence of sensitivity analyses. The outputs from the risk assessment methodologies, as they now exist, are not internally consistent; and they are less consistent or comparable) among the four sludge management options.

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REVIEW OF TECHNICAL DOCUMENTS

SUPPORTING PROPOSED REVISIONS TO EPA REGULATIONS FOR THE DISPOSAL/REUSE OF SEWAGE SLUDGE UNDER SECTION 405(d) OF THE CLEAN WATER ACT

REPORT OF

THE ENVIRONMENTAL ENGINEERING COMMITTEE

U.S. Environmental Protection Agency
Science Advisory Board
Washington, D.C.

January, 1987

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Table of Contents

I. EXECUTIVE SUMMARY 1

II. INTRODUCTION 7

III. REPORT ON THE SLUDGE DISPOSAL/REUSE RISK ASSESSMENT METHODOLOGIES

A. Overall Risk Assessment Methodology 8

B. Landfilling 17

C. Land Application and Distribution and Marketing 25

D. Incineration 39

E. Ocean Disposal 43

IV. APPENDICES

A. Roster of Committee Members Conducting the Review 47

B. Charge to the Committee 50

C. Summary of Purpose of Sludge Risk Assessments 51

D. Summary Matrix of Assumptions and Methods 53

E. Sensitivity Analysis of Crop Uptake Model Used in Land Application Methodology 61

F. References 76

I. EXECUTIVE SUMMARY

In August 1985 the Environmental Engineering Committee of the Science Advisory Board was asked by the Office of Water Regulations and Standards (OWRS) to review technical documents supporting development of EPA regulations for the disposal/reuse of sewage sludge under Section 405(d) of the Clean Water Act. The Committee was also asked by the Office of Marine and Estuarine Protection (OMEP) to review technical documents supporting revisions of the EPA ocean dumping regulations. The Committee chose to review the two sets of documents together, since they both dealt with a common subject, and since they shared, in some respects, a common methodology. This report, however, covers only the review of the OWRS documents, which consist of a set of risk assessment methodologies (1,2,3,4) for four sludge disposal/reuse options (landfilling, land application/distribution and marketing, incineration, and ocean disposal). The reviews of the OMEP documents are covered in separate Committee reports.

The following summary outlines the Committee's principal findings and recommendations. Details on each of these are found in Section III of this report.

are outlined

These methodologies begin the development of a framework for evaluating sludge management risks and for developing national criteria. The Committee encourages this approach. It is critical that these assessments be comparable so the decision maker can make the difficult evaluations and trade-offs in an informed and responsible manner. Outputs from the risk assessment methodologies as they now exist in the four documents, however, are not internally consistent, and they provide much less consistency or comparability between and among alternatives. As currently developed, these methodologies include unexplained omissions, conservative assumptions, a sole focus on MEI risks, the failure to consider the range of possible risks (i.e., distributions), and the absence of sensitivity analyses. The Committee recommends that further work to address these issues be performed before these methodologies are used to develop sludge management criteria.

The Committee is very supportive of good mathematical modeling and appropriate use of quantitative evaluation and management techniques to illuminate complex environmental protection issues. We recognize that, in addition to technical aspects, there are important economic, institutional, political, and social dimensions in decision making at all levels on such issues. This is both proper and realistic. It is desirable that decision makers be able to apply proper emphasis on both the technical and non-technical aspects. To the extent that risk assessment methodologies are consistent, sound, and well-supported, they will reduce excessive reliance on non-technical aspects which will, of necessity, prevail otherwise.

A. Overall Risk Assessment Issues

1. A working definition of risk, as used in these assessments, should be clearly articulated in the documents.

2. The methodologies themselves include assumptions about management practices and changes that will mitigate risks. These assumptions should be clearly presented in the documents.

3. Because these assessments include effects on species other than humans, the Committee believes that the use of the term "Most Exposed Unit (MEU)" is more appropriate than "Most Exposed Individual (MEI)."

Conservatism and Uncertainties

4. For the purpose of generating supposed "reasonable worst case" estimates, many subjective and conservative assumptions are made. When combined, they produce multiplicative conservatism which can become unrealistic. In addition, this technique produces inconsistent degrees of conservatism between management practices. As currently implemented, the reasonable worst case concept is misleading and inconsistent.

Throughout the risk assessment process, there should be more emphasis placed upon identifying and quantifying the probabilistic components of the analysis, as well as the probabilistic nature of the data. Data distributions should be used to generate an objective distribution of outputs. As a first step, EPA should conduct sensitivity analyses in order to understand the effects of conservative assumptions. In this way, the usefulness of the scenarios, the models, and the assessments can be ascertained. In the absence of probabilistic considerations, the decision maker cannot intelligently compare the relevant alternatives.

5. The risk evaluations are based upon the concept of the "Most Exposed Individual (MEI)." Sole reliance on the concept is flawed.

The MEI/MEU does not describe the total distribution of exposures and risks, even though such information is essential to predicting the range of risks of a disposal option. To the extent that distributions are evaluated, the technical manager will have a more complete understanding of possible outcomes and their likelihood.

The risk estimated for the MEI can be grossly exaggerated, and it is impossible to know from the information presented how extreme the MEI scenario is. Since the assumptions underlying the selection of the various MEIs differ, the degree of conservatism embodied in the various MEI exposure models also differs. Further, insufficient information is available to compare the relative degree of conservatism of one MEI with another. Consequently, it can be misleading to compare risks derived from one type of MEI with those of other MEIs due to the different premises used for different disposal options. The reliance on "worst-case" scenarios which pervades these documents needs to be reconsidered and here, as elsewhere, indicates the problems that stem from the absence of clear definitions and sensitivity analyses.

As an alternative to the MEI/MEU approach, these methodologies could estimate a distribution of exposures and risks. This alternative approach has been used in other risk assessments, including some adopted by EPA. Even if the MEI/MEU model is maintained, the analysis must be supplemented by an estimate of the distibution of exposures, and an estimate of where the MEI/MEU is found on that distribution.

6. The Committee has serious concerns about the uncertainties of the release and source characterization data for many of these sludge management practices. Sensitivity analyses should be conducted to evaluate these uncertainties. In the longer term, research should be conducted to generate improved data.

The models used for environmental release, and transport and fate characteristics, also contain many uncertainties. In addition, many of these models have not been compared with field data in terms of their expected accuracy and validity. These documents must provide the rationale for selection of all models. In some cases, the Committee believes that alternative models are more appropriate. Sensitivity analyses should also be used to address uncertainties within the chosen models. In the longer term, the Agency should stress model validation as a research priority.

Omissions

7. The methodologies do not identify and address all important pathways. The rationale for discounting potential releases and pathways is not presented. Unless adequate logic for such decisions exists, all potential pathways must be evaluated explicitly.

8. EPA should include an estimate of risks from handling and transportation.

9. The documents should clearly acknowledge that certain factors have not been addressed: exposure to pathogens, degradation products, products of incomplete combustion, ecosystem effects, toxicities of mixtures, reversability of effects, and pharmacokinetics.

Additional Documents

10. In order to ensure the consistency of the methods for developing national criteria, EPA should develop a synthesis document to compare assumptions incorporated and the relative uncertainties of the analyses. Such a document should also discuss the relationship of this analysis to sludge management regulations and decisions.

11. EPA should develop a users manual for users outside EPA Headquarters (in particular, State and Regional permit writers). This manual must strongly emphasize the uncertainties of these methodologies and the importance of accurate and applicable site-specific input data. This manual should stress that some models cannot be appropriately applied at some sites.

B. Landfilling

12. The two major routes of exposure of the "most exposed individual" (MEI) in the landfilling option are the drinking of contaminated well water and inhalation of vapors in the air. Other potential routes are not considered. Examples include surface water contaminated by runoff or leachate from ground water, bioaccumulation by edible aquatic organisms, the human ingestion of food from crops irrigated with contaminated ground water, or the potential use of closed landfills, if not for human food production, then for wildlife food chain exposures.

13. The assessment approach uses a three-tiered analysis which is both scientifically sound and practical. The Committee, however, in Section III.B., has identified a number of non-realistic assumptions or decisions which should be reviewed carefully by the Agency before the methodology is accepted, and before the methodology is used by EPA for policy decisions.

14. In the study under review, the CHAIN model is used for predicting the transport of contaminants in the unsaturated zone. The logic for this choice is not presented and, therefore, it is not possible to judge whether it is the appropriate model to use. The CHAIN model is not necessarily appropriate for unsaturated zone analysis unless there are known or estimated sequences to follow, such as for nitrogen.

15. The entire discussion of the nitrogen cycle in the document should be reviewed because it contains scientific inaccuracies.

16. The document assumes that the Toxicity Characteristic Leaching Procedure (TCLP) will be used to determine the concentration of toxic substances in the leachate from landfilled sludge. No supporting evidence that the TCLP procedure is applicable to municipal wastewater sludge was presented.

17. First-order decay rates, usually determined from aerobic studies, are assumed for degradable contaminants. Anaerobic conditions usually prevail, however, with the potential for underestimation of those contaminants which degrade at a slower rate under such conditions. The need for rate constants under anaerobic conditions should be stressed.

18. In the assessment of risks from the vapor contaminant pathway, the assumption is made that there is no degradation or attenuation of organic vapors in the soil cover through which they diffuse to the atmosphere. Ignoring this eliminates a major mechanism that can reduce concentrations of air emissions from a landfill. This potential pathway should be reassessed.

C. Land Application/Distribution and Marketing

19. The risk assessment methodology should address more than just the MEI; median or other central tendency values should also be used to evaluate exposure. The risk assessment document should re-examine the assumptions for the MEI along certain critical pathways and determine whether a significant portion of the exposed population exists at that risk level.

20. The document should clearly define dedicated land application to distinguish it from other sludge utilization/disposal methods.

21. The rationale used to derive the relative effectiveness factors for various exposure routes needs to be stated.

22. The fractions of food groups originating from sludge-amended soil are unrealistic. If all POTW sludges are used for food production, less than one percent of the agricultural land in the U.S. would be involved.

23. Past soil ingestion rate studies have produced inconclusive results, and were not quantifiable at the time this study was reviewed. Therefore, studies to characterize the soil ingestion rate should become a research priority.

24. The report includes a good discussion of the effect of sludge amendment on the physical properties of soils as they pertain to surface runoff. Additional discussion and guidance are required for a key parameter in the model: the adsorption partition coefficient, K_d.

25. Another area that remains unresolved is the probability of occurrence of the design instream concentration used. The methods used in the document are incorrect and need to be modified.

26. Justification for the use of the Universal Soil Loss Equation (USLE) for the calculation of runoff and erosion needs to be provided. It is recommended that the Agency consider the use of the "Chemicals, Runoff, Erosion, and Agricultural Management Systems" (CREAMS) model or the "Sedimentology by Distributed Model Treatment" (SEDIMOT II) model in place of USLE.

27. Section 7.3.1 describes the use of the TCLP to predict leachate concentrations from sludge-soil mixtures. The TCLP test was designed to simulate leaching and predict leachate concentrations of mixed wastes in landfills. The procedure has not been validated for use on sewage sludges, nor for simulating leaching from land application. In addition, TCLP tests using spiked samples should not be used in applications of the methodology.

28. In the vaporization pathway, no provision was made in tiers 2 and 3 to include factors for soil sorption and biodegradation of volatile organics. The equations for tiers 2 and 3 should be revised to include these two factors.

29. It is unrealistic to expect that the (human) MEI for volatile organics from land receiving sludge inhales 100 percent of his air from the sludge-applied area. This value should be revised downward.

D. Incineration

30. The document should provide a careful assessment of the state of knowledge with respect to total emissions from incinerators burning POTW sludges. This assessment should include products of incomplete combustion, as well as air emissions during unsteady or upset conditions.

31. The Agency should provide a technical rationale for the use of the particulate emission limit selected. The analysis should recognize that submicrometer particles, which are key to human exposures, are very difficult to remove from the effluent gas.

32. The Most Exposed Individual (MEI) concept, as applied to incineration, needs to be revised. Particular attention must be paid to short-term exposures (the methodology now assumes only long-term exposures), the definition of the MEI, and the multiplicative conservatism resulting from individual assumptions.

33. The Agency has correctly used standard methods for modeling the dispersion of pollutants. Cautionary language should be included, however, to note that these models have not been fully verified in the field, and that only limited data are available for this verification.

34. The document assumes that the ash and liquid output streams from the incineration process are treated. Unless the Agency can support discounting the risks of scrubber water/sludge and ash discharges, the Agency must explicitly evaluate the risks of these discharges.

E. Ocean Disposal

35. While the document presents a reasonable preliminary analysis of the initial mixing zone and far-field transport, other presently available hydrodynamic models of the coastal zone offer the possibility of a more realistic assessment of transport in the ocean.

36. The Agency should reconsider the assumptions about sludge settling, and should evaluate its potential significance by performing alternative modeling that includes settling.

37. It is assumed in the document that the entire mass of a pollutant behaves as if it were in the dissolved form. While this assumption is adequate for a preliminary evaluation, the more realistic case considering partitioning of a pollutant between the dissolved and particulate phases should be evaluated.

38. A major limitation in the document is its exclusive focus on impacts on pelagic organisms. Since settling may well be a factor in the long term, the potential impacts on the benthos must be evaluated.

39. Since only a limited number of ambient water quality criteria (AWQC) are available for salt water organisms, and since the number of disposal sites will be limited, the Committee believes that a better approach would be to use a site-specific evaluation using water column and suspended particulate bioassays.

40. The use of AWQC in this document is consistent with current approaches to water quality evaluations which have received extensive peer review. This approach, however, is based on laboratory data and does not by itself necessarily provide an accurate assessment of effects at the ecosystem level.

41. While the discussion of bioaccumulation factors (BCFs) is quite good, data limitations make it difficult to use BCFs to estimate human exposure potential.

II. INTRODUCTION

In August, 1985, the Science Advisory Board (SAB) was asked by the Office of Water Regulations and Standards (OWRS) to review technical documents supporting the development of regulations to be proposed (under Section 405 of the Clean Water Act) for the disposal/reuse of publicly owned treatment works (POTW) sludges. In late 1985, the Office of Marine and Estuarine Protection (OMEP) also requested that the SAB review technical documents supporting revisions to EPA ocean dumping regulations, which implement the Marine Protection, Research, and Sanctuaries Act (MPRSA). The latter set of documents was to be divided into two categories addressing, respectively, ocean disposal of sewage sludge (from POTWs) and ocean disposal of dredged materials. The reviews were assigned to the Environmental Engineering Committee, which decided to conduct the reviews for both Offices simultaneously, since the subject material was similar.

The Environmental Engineering Committee accepted the task, and augmented its membership with a number of consultants, including three members of the Environmental Advisory Board of the U. S. Army Corps of Engineers; three members of the SAB's Environmental Effects, Transport and Fate Committee; one member of the SAB's Environmental Health Committee; and other knowledgeable individuals. The Committee organized itself for the reviews by creating a number of subgroups, each dealing with one or more options/documents. A listing of the Committee membership, which includes the subgroups, is provided in Appendix A.

The Committee decided that, rather than issue one large report covering all reviews, it would issue separate reports on the disposal of dredged materials and on the disposal/reuse of sewage sludges. This report is confined to a review of technical material supporting development of criteria for the disposal/reuse of sewage sludges. The specific charge for this review appears in Appendix B.

Documents for review began to arrive in April, 1986, and on May 1-2, 1986 the Committee held its first meeting, at which it was briefed by both OWRS and OMEP. A second meeting of the Committee was held on June 10-11, at which it was briefed in more detail about the landfilling and land application options for sewage sludge disposal.

Subsequent meetings of the Committee were held on July 23-24, August 19-20, September 29-30, October 27-28, and December 15-16. The purpose of these meetings was primarily for Committee discussions and drafting of the Committee report. In addition, there were separate meetings of some of the subgroups. At all of the full Committee meetings, Agency staff were present to either brief the Committee or to answer questions and clarify the documents.

The Committee received outstanding cooperation on all aspects of the review from the staff of the Office of Water Regulations and Standards, the Environmental Criteria and Assessment Office, Cincinnati, and the Environmental Research Laboratory, Narragansett. Dr. Alan Rubin, OWRS, Dr. Larry Fradkin and Mr. Randy Bruins, ECAO, and Dr. John Paul, ERL-Narragansett, were particularly helpful.

This report, while largely drafted by the various subgroups, has been reviewed, discussed, and approved by the full Committee.

III. REPORT ON THE SLUDGE DISPOSAL/REUSE RISK ASSESSMENT METHODOLOGIES

The Agency has developed four documents that attempt to assess the risks associated with the disposal of municipal sludge by incineration, ocean dumping, landfilling, and land application/distribution and marketing. The purpose of the documents is to allow EPA to assess these alternative management methods in order to develop sludge management criteria (see Appendix C). The Committee has structured its observations to emphasize first, comments that apply to the overall model of risk assessment adopted across the four disposal options, and second, remarks specific to the assumptions and approaches of each of the four disposal options.

A. Overall Risk Assessment Methodology

Among the issues the Science Advisory Board has been requested to consider is the "...consistency of approach and assumptions, both within each disposal option and among the various methodologies." This section organizes these cross-cutting topics into four areas: 1) definitions, structure, and uses; 2) conservatism and uncertainties; 3) omissions; and 4) the need for additional documents.

EPA is to be commended for the aggregation of information in these methodologies on the environmental consequences of the four sludge management options. Evaluation of the options by considering source characteristics, pathways of environmental transport and fate, and human and ecological exposure patterns should enable public decision makers to make better decisions on sludge management and disposal.

It is critical that these assessments be comparable so the decision maker can make the difficult evaluations and trade-offs in an informed and responsible manner. Output from the risk assessment methodologies as they now exist in the four documents, however, are not internally consistent, and they provide much less consistency or comparability between and among alternatives.

The Committee is very supportive of good mathematical modeling and appropriate use of quantitative evaluation and management techniques to illuminate complex environmental protection issues. We recognize that, in addition to technical aspects, there are important economic, institutional, political, and social dimensions in decision making at all levels on such issues. This is both proper and realistic. It is desirable that decision makers be able to apply proper emphasis on the technical and non-technical aspects. To the extent that risk assessment methodologies are consistent, sound, and well-supported, they will reduce excessive reliance on non-technical aspects which will, of necessity, prevail otherwise.

1. Definitions, Structure, and Uses

An immediate problem arises from the absence of a definition of "risk" that permits a clear evaluation of risks in the four documents. Even a minimal definition, such as risk being "the realization of unwanted, negative consequences of an event," could help the audience of the reports follow the arguments of a new risk assessment approach. Although many differences, even within EPA itself, exist in the definition of the risk assessment, certain conceptual boundaries must be established about how to define the nature, extent, duration, magnitude, and severity of potential risks to public health and the environment from exposure to hazardous contaminants arising from sludge management. Clear distinctions should be drawn between risk assessment and such overlapping concepts and methodological strategies as "hazard assessment," "dose-response models," "vulnerability analysis," "risk-benefit analysis," or "exposure assessment." (In the course of our review it became evident that the four risk assessment documents focus primarily on exposure issues, relying on existing sources for hazard identification and dose-response information.)

Once a definition of risk and its basic dimensions are specified, the text should then outline how the various assessments are made, progressing from hazard identification, to dose-response assessment, to exposure assessment, and finally to risk characterization. Although the four documents present a basic outline (Figure 1-1), the Committee believes that a revised algorithm (such as Diagram 1) can better summarize the sequence of the assessment process. (Note that the letters in each step can be used for the comparisons across disposal options -- see Appendix D.) Diagram 1 summarizes the Committee's understanding of these methodologies and their use in developing national criteria.

Although not strictly part of these assessments, or the Committee's charge, these methodologies have several implications for risk management that concern the Committee. First, the methodologies themselves include assumptions about management practices and changes that will mitigate risks. These changes might include variable application rates, enhanced disposal designs, and environmental monitoring schemes. The documents must clearly present assumptions about current practices and changes.

Second, regardless of EPA's intentions, these methodologies will be used by utility managers as part of their attempts to evaluate and compare sludge management options. EPA should consider this when designing and documenting these methodologies. For example, it would be useful to develop for such "users" a flow chart with "sewage sludge" flowing into the top of a decision diagram and splitting off to deal with decisions, questions, and judgments which lead to or away from a consideration of one or more of the four disposal options. There should be enough decision and logic blocks to provide all of the pathways for environmental contamination, human health effects, ecosystem effects, and all other impacts that are possible or probable for all disposal options. Rather than relegate such concerns to future implementation efforts, the Committee believes the Agency should emphasize close and early coordination between regulatory development and implementation efforts.

2. Conservatism and Uncertainties

The methodologies contain serious problems with the treatment of uncertainties, probability, and conservatism. These problems affect the reliability and the consistency of the assessments.

For the purpose of generating supposed "reasonable worst case" estimates, many subjective and conservative assumptions are made. When combined, they produce multiplicative conservatism. In reviewing the various disposal options, we cannot determine if reasonable worst cases are reasonably determined, or whether the scenarios presented lie at the extremes of conservatism to the point of being unrealistic. In addition, this technique produces inconsistent degrees of conservatism between management practices. As currently implemented, the "reasonable worst case" concept is misleading and inconsistent.

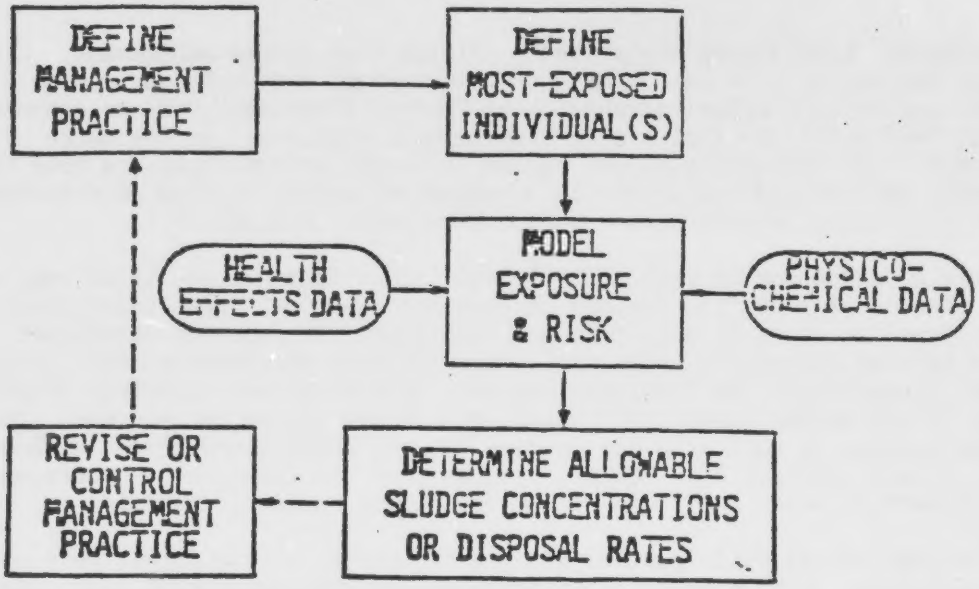
DEFINE MANAGEMENT PRACTICE
DEFINE MOST-EXPOSED INDIVIDUAL(S)
HEALTH EFFECTS DATA
MODEL EXPOSURE & RISK
PHYSICO-CHEMICAL DATA
REVISE OR CONTROL MANAGEMENT PRACTICE
DETERMINE ALLOWABLE SLUDGE CONCENTRATIONS OR DISPOSAL RATES

Figure 1-1: Criteria Derivation Procedure (Source: Refs 1-4)

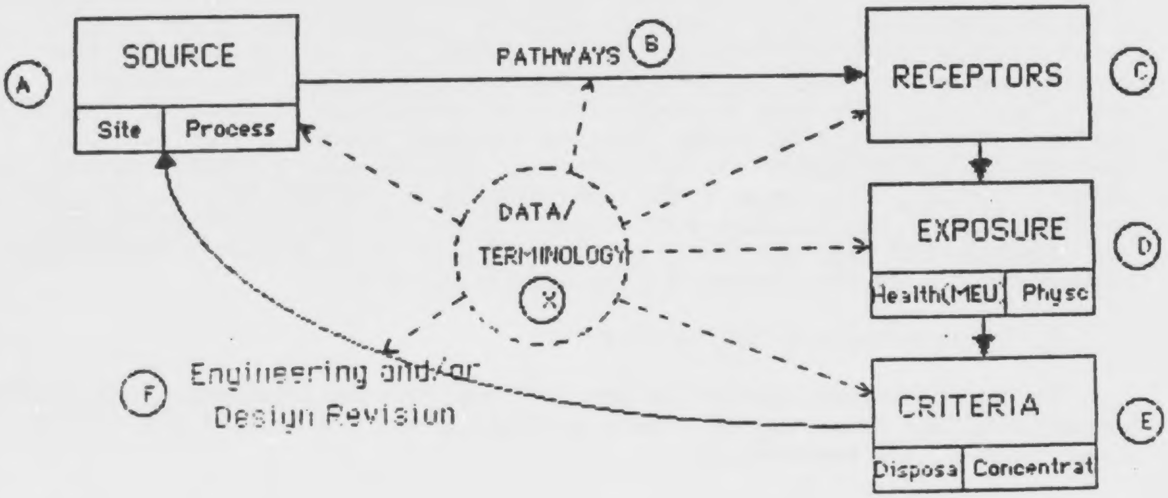
A
SOURCE
Site
Process
PATHWAYS
B
RECEPTORS
C
EXPOSURE
Health(MEU)
Physc
D
DATA/
TERMINOLOGY
X
CRITERIA
Disposa
Concentrat
E
F
Engineering and/or
Design Revision

Diagram 1: Flowchart for Criteria Derivation Within Each Disposal Option

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Many of the "worst case scenarios" seem to protect against a very extreme situation and appear to border on the unreasonable. We recommend that before the specific risk assessment methodologies be used to develop criteria, detailed sensitivity analysis studies be conducted to determine a) the reasonableness of the respective worst case scenarios; b) the uncertainties that will be associated with typical results; and c) the probability distribution of exposures and risks that will occur as a result of specific assumptions and scenarios.

Throughout the risk assessment process, there should be more emphasis placed upon identifying and quantifying the probabilistic components of the analysis, as well as the probabilistic nature of the data. In this way, the usefulness of the scenarios, the models, and the assessments can be ascertained. To the extent that this is done, the technical manager will have a sounder understanding of the distribution of possible outcomes and their likelihood. In the absence of probabilistic considerations, the decision maker cannot intelligently compare the relevant alternatives.

One technique for probabilistic uncertainty analysis of a scientific model is Monte Carlo analysis. With this method, the model is replicated by choosing inputs and parameters from distribution functions. The resulting distribution of model outputs are analyzed. An example of Monte Carlo analysis applied to evaluating the environmental impacts of land application is presented by Kaufman and Haith (5).

The risk evaluations are based upon the concept of the "Most Exposed Individual (MEI)." Although the MEI approach is sometimes used within EPA, sole reliance on the concept is a weak point in these risk assessment methodologies. The concept, as used in these methodologies, suffers three important limitations:

a) The MEI does not describe the total distribution of exposures and risks, even though such information is essential to predicting the risk of a disposal option. Are exposures spread broadly and evenly among the target population, or realized only by a few?

A possible exposure distribution is illustrated in Diagram 2. To provide a framework for discussion, three general shapes for the exposure distribution are proposed (Diagram 3). Type A depicts a situation in which almost all the population receives a zero or nondetectable exposure, represented by a probability mass at zero. A small subpopulation is exposed with the indicated distribution. Type B represents a situation in which all members of the population are exposed, but the distribution is highly skewed, so that most receive small exposures while a few receive very high exposures. Type C depicts the case where exposures are more broadly and evenly spread throughout the population.

The use of this framework for classification of the different exposure pathways and their associated MEIs can help provide better characterization and comparison of the different disposal options. For example, the following classifications are suggested:

1. Exposure by consumption of fish caught near the ocean disposal site appears to follow a Type A distribution;

2. Exposure to residents breathing in the vicinity of a sludge incinerator is most likely Type B;

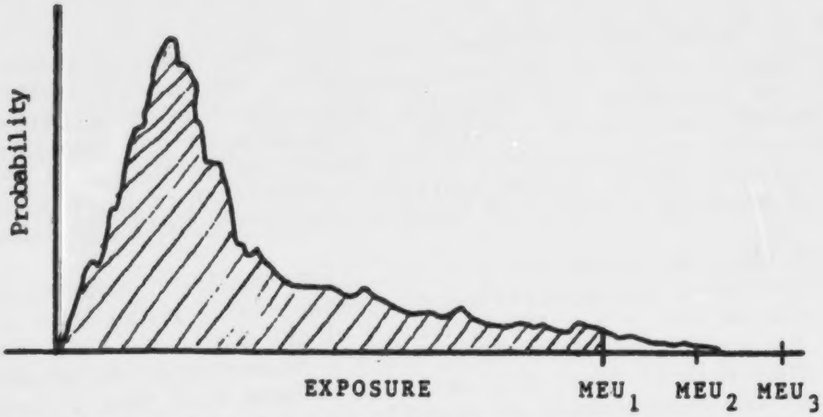

Diagram 2: Typical exposure distribution profile with selection of increasingly conservative MEU. (Shaded area represents relative fraction below MEU).

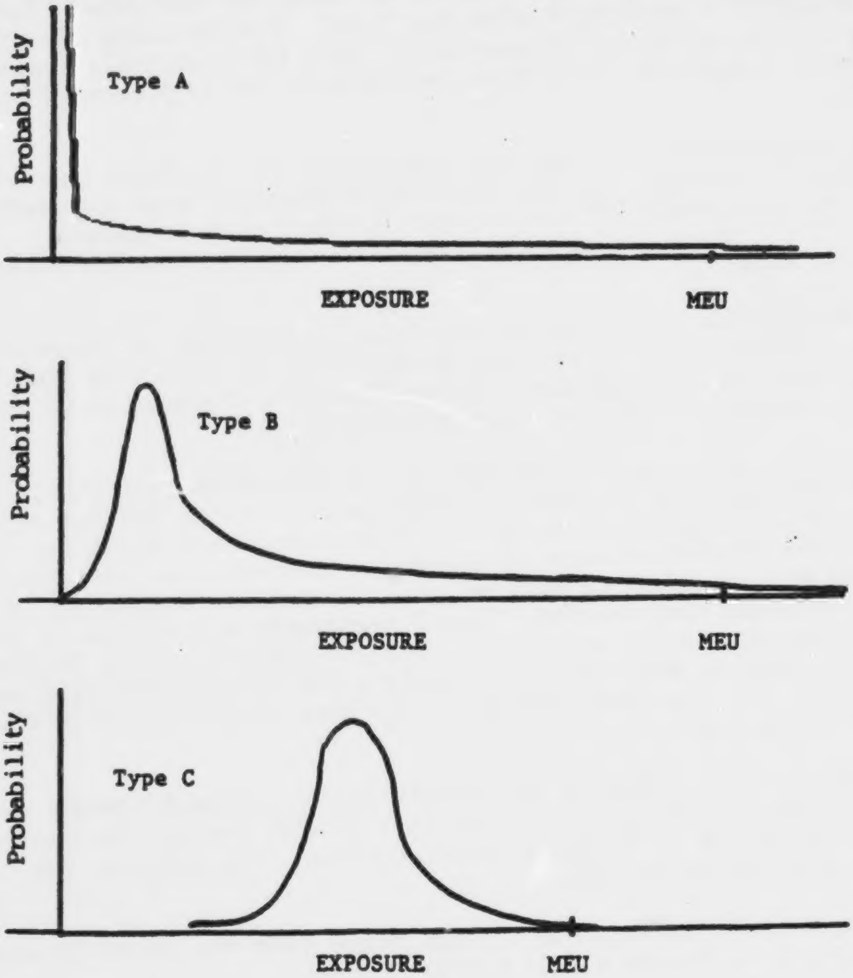

Diagram 3: Representative exposure distribution profiles.

3. Exposure through the food supply from sludge applied to cropland is likely to be Type C.

By characterizing the different exposure pathways in this manner, the selected MEIs can be considered relative to the exposures to the overall population. This will help elucidate some of the critical policy trade-offs inherent in the use of the MEI approach. For example, referring to Diagram 3, one could decide that even though the MEI exposure in the Type B curve is higher than that in the Type C curve, the fact that the Type C exposure occurs more frequently through the population (with a higher average exposure) can cause one to prefer the Type B option. The shape of the associated dose-response curve will be an important factor in this decision as well, i.e., is it threshold or nonthreshold, linear or nonlinear? The identification of exposure distribution profiles thus provides an improved basis for risk management.

To develop the improved risk assessment proposed, EPA should conduct sensitivity analyses and use probability distributions where possible (as discussed above). EPA should also consider characterizing the selected receptors and MEIs for the different disposal options in terms of the general types suggested above.

b) The risk estimated for the MEI can be grossly exaggerated, and it is impossible to know from the information presented how extreme the MEI scenario is. How conservative or extreme is the selection of the MEI; that is, how far out on the tail of the exposure distribution is the MEI? Is it an exposure realized by 1 in 100, 1 in 10,000, 1 in 1,000,000; or is it out beyond a conceivable upper bound to the distribution?

Since the assumptions underlying the selection of various MEIs differ, the degree of conservatism embodied in the individual MEI exposure models also differs. Further, insufficient information is available to compare the relative degree of conservatism of one MEI with another. Consequently, it can be misleading to compare risks derived from one type of MEIs with those of other MEIs due to the different premises used for different disposal options. The reliance on "worst-case" scenarios which pervades these documents needs to be reconsidered and here, as elsewhere, indicates the problems that stem from the absence of clear definitions and sensitivity analyses.

For example, the landfilling document assumes that the MEI will inhale 100% of his air from the landfill (page 5-23) at a rate of 20m^3/day, which is more characteristic of a person performing light to moderate work. No account is taken of dilution of the air contaminants due to changes in wind direction or wind speed. The intake of contaminants from water is assumed without reference to the source of actual water supplies.

The land application and distribution and marketing methodology includes a very conservative scenario in which a ten kilogram (twelve month old) child directly ingests sludge (applied as fertilizer). For food crop effects, the methodology extrapolates plant uptake factors between species. It also assumes the highest consumption rates for individual food crops.

The MEI for ocean disposal of sludges also assumes a number of conditions which are questionable. While the behavior described in Case 1 has been documented on the part of recreational fishermen, the Committee seriously questions the annual return time of such an event. In addition, the 1,500 km^2 home range for large swordfish and tuna is contrary to what is known from recovery data from marked fish, which suggest that these species range over much wider areas. Also, the larger marine fish typically require much longer periods to reach equilibrium concentrations, during which time they would be expected to traverse greater ocean distances.

For municipal sludge incineration, the exposure source is presumed to be particulate emissions from the incinerator. The exposure calculations assume that all particulates dispersed by incineration are of a size enabling complete uptake by the lung. (It is not clear whether emissions other than particulates are considered, although examples cited later in the text do refer to substances expected to occur mostly in the vapor phase.) The MEI is assumed to live at the site of the maximum annual ground level concentration from birth to death at 70 years, residing at that location for 24 hours per day, presumably without ever living indoors, or assuming that pollutant concentrations in indoor air are the same as those outdoors.

c) The emphasis of risk assessment in EPA is to evaluate effects on human health and the environment. The use of a "Most Exposed Unit (MEU)" is more appropriate than MEI, because species other than humans may be affected.

It is critical, particularly because of the state of knowledge about many of the processes being evaluated and because of uncertainties and variations in input parameters, that EPA explicitly present and evaluate uncertainties. The Committee has serious concerns about the uncertainties of the release and source characterization data for many of these sludge management practices. For example, there are large uncertainties and few measured data on sludge landfill leachates or sludge incinerator stack emissions. Although the issues related to uncertainties are complex, and many of them are beyond definitive resolution at present, this should not preclude elaborating these important issues to the fullest possible extent.

The Agency's practice has been to rely on different models to estimate exposure in different media. The degree of validation and the expected accuracy for the various exposure models differ widely. A systematic discussion of why all selected models were chosen should be provided. If the alternative disposal options are to be evaluated in an equivalent manner, then the potential errors and biases of each model should be addressed through sensitivity analysis as part of the methodology. The models used for environmental transport and fate characteristics also need to be compared with field data in terms of their expected accuracy and validity. Model validation should be stressed as a research priority.

3. Omissions

These methodologies and decisions about national criteria incorporate assumptions about "current" practices and changes in practices that may mitigate risks. Without discussion of possible mitigation strategies (such as the use of lined landfills, for example), it is impossible to judge whether the methodologies can adequately represent all relevant permutations of the four sludge management practices. In addition, environmental monitoring should be considered as one possible component of risk mitigation strategies. Such monitoring programs could incorporate certain triggering mechanisms for corrective actions.

The methodologies do not identify and address all important pathways. The rationale for discounting potential releases and pathways is not presented. Unless adequate logic for such decisions exists, all pathways must be evaluated explicitly.

Similarly, certain problems seem to be either neglected or treated in only a cursory fashion. For example, the selection of chemical agents to serve as the basis of a risk assessment is a central issue; the document should clearly reference the study conducted to make these selections. Also, how should the possibility of interactions be considered? Unexpected interactions are the most vexing questions posed by the kinds of complex mixtures inherent in sludge disposal, and should be recognized in any effort at risk assessment. EPA is actively engaged in evaluating different approaches to estimating the health risks of complex mixtures. Decisions about adverse health and ecological consequences must incorporate decisions about how to combine data, and how to evaluate multiple chemical exposures.

Exposure pathways for the transport of the sludge to the disposal site should also be incorporated, at least qualitatively, and when important, quantitatively. These pathways should include the risk of accidents and other pertinent items.

The documents should clearly acknowledge that certain factors have not been addressed: exposure to pathogens, degradation products, products of incomplete combustion, ecosystem-level effects, toxicities of mixtures, and pharmacokinetics.

The sludge disposal assessment methodologies use existing methods, developed by various offices within EPA, to protect primarily against adverse human health effects. However, there is little information about comparative assessments of human carcinogens, human non-carcinogenic toxicants, and ecological effects. The assumption that programs designed to protect certain aquatic species also protect total aquatic ecosystems is backed only by fragmentary evidence. EPA has been slow to develop risk assessment methods for the protection of wildlife and terrestrial ecosystems. This may constrain eventual comparisons between options.

Bioconcentration, which refers to the amplification of water concentration of contaminants, is discussed at length, but biomagnification is only mentioned. This process, however, which embodies the successively higher concentrations achieved by a contaminant as it ascends the food chain, is at least equally significant.

The crucial role of pharmacokinetics has been emphasized in many SAB reviews, but is only superficially acknowledged in the models, as in the Relative Effectiveness (RE) value. Yet, the difference between expressing ambient concentrations in terms of annual averages and recognizing the possible contributions posed by high transient peaks could be critical in certain instances. EPA recognizes such differences by the way in which it specifies some standards, for example, ambient air standards.

Ideally, risk assessment should also embody interactive routes of exposure, diachronic consequences, and synergistic effects. The present documents, with their strong emphasis on singular threshholds, diminish consideration of such background factors and their influences on toxic potency and ecosystem functioning. We recognize that the question of cumulative impacts compounds the present conceptual and methodological difficulties. No discussion of risk assessment, however, should ignore the far-reaching importance of multiple effects and interactions.

4. Additional Documents

In order to ensure the consistency of the methods for developing national criteria, EPA should develop a synthesis document to compare assumptions incorporated and the relative uncertainties of the analyses. Such a document should address the comparative risks between ecological effects, systemic toxicity, and carcinogenic responses within and among disposal options. Such a document should also discuss the relationship of this analysis to sludge management regulations and decisions.

One of the most important tasks of our review and the proposed synthesis document is that of evaluating consistency of approaches across the various disposal options (or management practices) in the four documents. An illustrative matrix was constructed (see Appendix D) to summarize some of the relationships between disposal options and the dimensions of the assessment process suggested in our Diagram 1. Such a matrix, when completed and improved by EPA, as part of the synthesis document, could assist users and decision makers in understanding the difficulties in comparing options and the results of the four individual assessments.

In addition, EPA should develop a users manual for users outside EPA Headquarters (in particular, State and Regional permit writers). This manual must strongly emphasize the uncertainties of these methodologies and the importance of accurate and applicable site-specific input data. We concur with the concept of allowing the use of sound site-specific data, when available, in place of national standards. In addition, this manual should stress that some models cannot be appropriately applied at some sites.

B. Landfilling

The comments are presented in three parts: general comments; substantive comments specific to statements in the document; and editorial corrections, typographical errors, and similar comments.

1. General Comments on the Methodology

a. Pathways

The report presents a proposed methodology for assessment of the human health risks associated with the disposal of municipal wastewater treatment plant sludges by landfilling. The two major routes of exposure of the "most exposed individual" (MEI) are the drinking of contaminated well water and inhalation of vapors in the air. The assumption is made that surface runoff management can be depended upon to prevent surface water contamination. Also, there is no recognition of the possibility that leachate percolating through the ground water might reach surface waters, and that bioaccumulation by edible aquatic organisms could result in a greater exposure to some individuals than the two exposure routes included in the analysis.

Another route not considered is the human ingestion of food from crops irrigated with contaminated ground water, or from potential use of closed landfills, if not for human food production, then for wildlife food chain exposures. The assumption is made (page 3-5) that risk evaluations based on drinking water concerns will result in the most restrictive sludge concentration criteria for the ground water pathway. This may be a correct assumption for ground water, but it also seems to be used to justify not looking at the crop uptake pathway as a potential human exposure route. Figure 3-3 does not contain any crop uptake pathway; the potential routes of off-site migration stated on page 3-1 do not indicate a potential concern with crop uptake, and no comment on the potential crop uptake pathway appears in Section 3.

Sludge landfills are a disposal sink for contaminants in the sludge. Nonmobile slowly degradable organics and inorganics such as metals will remain in the landfill after it is closed. The concentration of these contaminants at the sludge landfill sites will be much greater, due to the higher application rates, than occurs from the land application of sludges to food chain crops. After closure, it is possible that food chain crops can be grown on such sites, the roots of the crops can penetrate into the decomposed sludge layer, and the accumulated contaminants, such as the metals, can be taken up by the crops.

No consideration is given to the potential for residents living near the landfill to be exposed to air emissions during the operational stage when liquid or semi-liquid sludge is being placed in the trench and is yet uncovered. This hazard is greatly reduced if dewatered sludge with 20% to 40% solids is being landfilled.

EPA may consider these exposure routes to be unimportant. If so, the logic for such a conclusion should be included in Chapter 3. The absence of any discussion of the aquatic food and crop and aerosol pathways of exposure makes it appear that EPA simply neglected potentially relevant pathways.

b. Assumptions

The assessment approach uses a three-tiered analysis which is both scientifically sound and practical. The assumption is made that if the concentration of toxic substances at an upgradient point is easily computed and is shown to be on the safe side of the health risk criterion established for that substance, then landfilling is permitted. This is equivalent to assuming that any further transport will decrease the concentration of the toxic contaminant. One exception to this general premise would be the possible bioaccumulation in exposed organisms. Otherwise, the use of the three-tiered computation is useful and practical.

Throughout the document, decisions are justified on the basis that the assumption or approach, even if it is not totally realistic, is conservative and therefore protects human health and the environment. This results in heaping conservatism upon conservatism. This can result in over-conservatism beyond reasonableness, and the three-tiered analysis should certainly not be so conservative as to be unrealistic; to do so will result in excluding some sludges from landfilling which do not need to be excluded. Many of the specific comments suggest where non-realistic assumptions and decisions appear to have been made.

c. Consistency

We have been requested to consider the consistency with which EPA regulatory procedures are being developed. In this risk assessment methodology, consideration is given to the time of travel and the degradation which occurs in the unsaturated zone. This Committee previously reviewed another document developed for decision-making about banning of landfilling, in which contamination of ground water by leachate was also involved (6). In that document, the "worst-case" assumption was made that there was no unsaturated zone because the bottom of the landfill was at the ground water table. The Committee believes this apparent inconsistency in procedure is justified by the fact that the present document presents a methodology for risk assessment which must be applicable to cases where there may or may not be an unsaturated zone. The previous document presumed the worst case as a decision tool and left the burden on the applicant for a petition to show that the unsaturated zone provides for further reduction in contaminant concentration. We believe the different purposes of these two analyses justifies the different assumptions regarding the effect of the unsaturated zone.

Another methodology for the evaluation of the landfilling alternative to ocean disposal of sewage sludge (7) models the transport of leached contaminants from a trench sludge-only landfill to the ground water table using the Pesticide Root Zone Model (PRZM) and transport in the saturated zone with the Analytical Transient One-, Two-, and Three-Dimensional Simulation of Waste Transport in the Aquifer System Model (AT 123D). In the study under review (1), the CHAIN model is used for predicting the transport of contaminants in the unsaturated zone. There is no discussion, however, of the basis for its selection in preference to the PRZM model. We note also that this study uses the MINTEQ model to handle the chemical interactions when the leachate is mixed with the ground water flow in the saturated zone. Even though the MINTEQ model is limited as discussed below, this may still be a better estimate of the effect of the mixing than the assumption that the contaminants are conservative and that the ground water dilutes the contaminants in a mass balance. We recommend that justification for the choice of models, including the rationale for not selecting other models, for example, those used by the Integrated Environmental Management Division of EPA to evaluate sludge landfilling (7), be provided.

2. Specific Comments

a. Page 2-1: The discussion notes (line 14) that the sludges include "raw ... solids from primary, secondary or treatment processes." Technically such sludges should be referred to as undigested solids. The term raw solids usually indicates settled primary solids only.

However, the real question relates to the practice of landfilling undigested sludges. The general requirement for land application of sludges is that the sludges be treated by a process to significantly reduce pathogens (PSRP) before land application. Is the statement starting on line 14 consistent with established EPA policy? Are sludges that are not treated by a PSRP allowed to be landfilled? These issues should be clarified.

b. Page 3-1: The second route of off-site migration states that the sludge is pumped in a trench landfill as a slurry. This statement is inconsistent with the assumption stated on the top of page 2-2 that the landfilled sludges will be dewatered to have a solids content of 20-40%. Such dewatering does not result in a pumpable slurry.

There are other locations in this document where there are statements that suggest that the sludge is a slurry and others where it is stated to be a dewatered solid. Such inconsistencies must be resolved.

c. Page 3-9: The sentences at the top of the page infer that all volatilization will occur prior to the sludge being disposed of in a landfill. The logic for this is not obvious, especially since the document infers in several places that the sludge is deposited as a slurry.

Subsequent statements on page 3-9 infer that vapor losses will occur and that a methodology is provided to predict vapor concentrations at the site boundary. The apparent inconsistency in assumptions about possible volatilization losses in a landfill needs correction.

The second sentence at the top of the page, "Volatile residues can, therefore, be assumed to result from the sludge-contaminant interactions that prevail," appears to be either a motherhood statement or a highly confusing one. The meaning and purpose of the sentence is not clear and serves to confuse rather than clarify the issue.

d. Page 4-4: Line 9 from bottom - The sentence reads, "For nonbiodegradable contaminants, the concentration is unchanged through the unsaturated zone." No definition of these nonbiodegradable contaminants is provided to substantiate the validity of the statement.

The sentence is incorrect for many nonbiodegradable contaminants. Some organics can hydrolyze, others can sorb to the soil, and geochemical reactions can occur. The logic and validity of the statement is obscure and doubtful.

e. Page 4-5: The first sentence indicates that the CHAIN model is used to predict contaminant concentration at the base of the unsaturated zone. The logic for the choice of this model is not presented, and therefore it is not possible to judge whether it is the appropriate model to use.

The CHAIN model is not necessarily the appropriate one for the unsaturated zone analysis unless there are known or estimated sequences to follow such as for nitrogen. How relevant this model is to landfill situations where organic contaminant pathways are unknown or are not important is unclear. Has it been validated? Justification for use of this model must be provided.

In addition, volatilization is not included as a component of the model. Contaminant pathways that contain a constituent that is volatile or that may sorb may not be handled well by the CHAIN model. Other models that do contain a volatilization component and that do account for contaminant transport are available and also could have been used (8,9,10).

A response may be that the CHAIN model provides a conservative risk assessment analysis in that the results may be an overestimate. This may be true, but a better approach is to use realistic models and assumptions rather than less realistic ones that pile unknown degrees of conservatism on conservatism.

f. Page 4-5: Lines 10 and 11 from bottom - These two sentences refer to an "application." This document supposedly describes the methodology that can be used by the Office of Water Regulations and Standards to develop regulations and standards. This document is not a guidance manual. We would not be comfortable with its use in permitting. Hence, references and words that indicate how a regulatory office can use the methodology for permitting purposes are inappropriate and should be removed here as well as elsewhere.

g. Page 4-6: Table 4-1 - The assumption that total Kjeldahl nitrogen (TKN) is completely converted to nitrate beneath the sludge landfill is scientifically inaccurate. The statement that overprediction occurs because some organic nitrogen does not break down misses the key point. The key point is the following: Negligible concentrations of the mobile form of nitrogen (nitrate) exist in anaerobically digested sludges to leach from the landfill. Nitrates are formed only if oxidized conditions exist in the landfill, i.e., dissolved oxygen is present, and if nitrifying bacteria are present. Therefore, if nitrogen leaches from the landfill, it will leach mainly as the ammonium ion. The ammonium ion is positively charged and will sorb to the soil particles, i.e., take part in the cation exchange process. It, therefore, will be retarded by the exchange process. Depending upon the sorption and exchange capacity and redox potential in the subsoils, the ammonium ions will be more or less retarded in reaching the ground water.

It is not likely that dissolved oxygen will exist in the landfill or in the pores of the unsaturated soil beneath a sludge landfill. If ammonium migrates, so will some dissolved organics. The oxygen demand of such organics will result in the oxygen in the unsaturated zone being used by the local bacteria as they metabolize the organics. This means that anoxic conditions will exist in the unsaturated zone. Therefore, it is unlikely that dissolved oxygen will be present; and it is unlikely that nitrates will be formed.

Thus the assumption results in a gross overprediction of the potential nitrogen problem in the ground water. As stated earlier, the assumption is unrealistic and casts doubt on the credibility of the methodology for the ground water pathway.

Similarly, the assumption that the metals migrate through the unsaturated zone in the oxidized state appears to be doubtful because of the anoxic conditions which prevail. The possibility that metals are complexed by organic compounds should be considered. Other contaminants, including organics, will not be subject to the same degree of sorption.

h. Page 4-6: The assumption of steady water flow in the unsaturated zone is not necessarily a conservative assumption. Intermittent, pulse flow can lead to more rapid transport due to an increase in the relative size of mobile vs. immobile water zones and increased macropore channeling.

i. Page 4-9: The risk assessment methodology begins with use of the Toxicity Characteristic Leaching Procedure (TCLP) to determine the concentration of toxic substances in the sludge contained in the landfill. No supporting evidence that the TCLP procedure is applicable to municipal wastewater sludge is presented.

j. Page 4-12: Line 10 - The statement is made that TKN degrades to nitrate over time. This is true for many situations but is not realistic for the sludge landfill scenario (see comment g.).

k. Page 4-13: In the sentences below Equation 4-4, first-order decay mechanisms are assumed for degradable contaminants. Literature values for organic decay constants presented in Table C-2 generally were obtained from aerobic studies. As noted earlier (comment g.), anaerobic conditions are likely to exist below sludge landfills. The available decay rate data base, therefore, may not be appropriate for the proposed methodology.

The difference between aerobic and anaerobic decay rates is not trivial. Decay rates generally are greater under aerobic conditions than under anaerobic conditions. In this case, the lack of realization of what occurs below sludge landfills (i.e., anaerobic conditions) may lead to aerobic decay rates being used. This would result in a nonconservative situation since the methodology would assume greater decay and lower contaminant concentrations than may occur.

The decay-rate assumption ignores reality and is internally inconsistent with other assumptions and statements made in this document. On page 4-26, it would be proper to provide recognition that degradation will occur and reference the section in which it is discussed.

Furthermore, the assumption is made that the degradation products produced during transport through the unsaturated zone are nontoxic, or at least that every contaminant in the leachate degrades to nontoxic products at a rate described by the decay rate constant. When toxic intermediates are known to result, the proposed method assumes the degradation rate is zero, for example, as in the case of tetrachloroethylene.

l. Page 4-15: Criteria for selection of a procedure for computing the time of travel in the unsaturated zone are presented on page 4-15. The priority of the criteria may not have been intended to be indicated by their order of presentation, but if it is, the priority seems to be reversed. We believe the appropriateness of the method is most important and do not recognize any compelling reason why "specialized site studies" should not be conducted to support an application.

Further, we see a real danger in development and use of a method just because it is sufficiently simple that it "can be used by persons whose backgrounds are varied and whose training does not cover the broad spectrum of disciplines involved." Use of a complex model requiring sound judgement in selection of a host of realistic input parameters by unqualified users is bound to lead to erroneous output. However, substitution of an overly simplistic model which is quite inadequate in simulating the complex environmental system, just for the purpose of simplifying the aquisition of input data so that unqualified persons can put the model to work, is equally falacious. In fact, there is real danger that the output will be assumed to be valid when it is not. Most inappropriate is the adoption of an overly simplistic model just so that unqualified persons can use it. This criterion is thoroughly inappropriate for selection of a model for time of travel in the unsaturated zone. We can not agree with this criterion as a basis for selection of a model. Selection must be based on more valid criteria.

m. Page 4-26: In the discussion of contaminant travel time, degradation apparently is not considered. Sorption is considered the only retardation or loss mechanism that will occur in the unsaturated zone.

n. Page 4-28: Errors in determining the order of a reaction do not necessarily lead to over- or underprediction of degradation. That depends on the values of the coefficients determined and the relative residence times in the laboratory and the field. The really important questions are whether degradation of any sort occurs in the field, and whether significant time is required for acclimation by degrading organisms.

o. Page 4-29: Line 3 - The degradation rate data referred to in Appendix C of the document are all likely to be based on aerobic conditions and are not appropriate for the anaerobic conditions below the landfill (see comment k.).

p. Pages 4-29 and 4-30 - The nitrogen conversion assumptions described on these pages are unrealistic for sludge landfills (see comment g.) and should be changed.

The discussion on page 4-29 for nitrate (if it is present at all) being reduced to nitrogen gas lower in the unsaturated zone is strained. Denitrification occurs when bacteria metabolize an organic substrate in the absence of dissolved oxygen and use nitrate as the hydrogen acceptor. If all the ammonia is oxidized to nitrate in the unsaturated zone (not very likely), it must be assumed that any organics also will be metabolized. Therefore, there will be little substrate to be metabolized and to result in denitrification.

The entire nitrogen conversion logic should be carefully re-examined and modified to represent realistic conditions beneath a sludge landfill.

q. Page 4-31: Middle of first paragraph - Provide a reference for assuming that dispersion is one-tenth the depth to groundwater times the velocity.

r. Page 4-33: The MINTEQ model is an equilibrium model. The migration of the metals depends on the sulfur species present, and the kinetics of the sulfur reactions are too slow to be able to assume that equilibrium exists. Table 4-4 shows that sulfate predominates in the ground water background, but the sulfur in the leachate may be primarily sulfide because of the anoxic conditions. The assumption that the leachate will not change the chemistry of the ground water may be conservative.

Some discussion of the physical processes affecting chemical speciation in the MINTEQ runs would be useful. For example, indicate which precipitates are being formed at the different pH-Eh (redox) values.

The document presents the output for several runs on the MINTEQ model. This is for the purpose of permitting an applicant to select contaminant concentrations based on matching the ground water conditions of a given run to those on the site of interest. It is recognized that many applicants will not have the resources to make their own runs on the MINTEQ model, however, for those who do, a site-specific run of the model is recommended.

s. Page C-20: State the temperature assumed in computing the dimensionless Henry's Law constant (H') in Table C-5.

t. Page C-45: Explain why saturated zone copper decreases with an increase in unsaturated zone copper. Is it a numerical error or a physical process?

u. Page 5-4: In the assessment of the vapor contaminant pathway risks, the assumption is made that there is no degradation of organic vapors in the soil cover through which they diffuse to the atmosphere. This may be conservative, but it ignores the reality which should be incorporated into the Tier 2 and 3 methodologies. It also seems inconsistent with the methodology for ground water contamination by the leachate. Granted that the flux rate is not time dependent, the flux from the soil cover surface should be less than the flux rate at the sludge surface due to degradation within the soil cover. Many studies have demonstrated that degradation of gases and vapors does occur in the soil. Ignoring degradation during volatilization through soils ignores a major mechanism that can reduce the concentration of air emissions from a landfill.

v. Page 5-5: The assumption that loss rate is controlled by diffusion ignores degradation (see comment re: page 5-4) and is not the most appropriate one for landfilling.

w. Page 5-10: Determination of the emission rate of vapors from the soil as described on page 5-10 is based on an equation attributed to an EPA contractor which was published in a report to EPA (Environmental Science and Engineering, 1985). No reference is made to publication of the equation in the peer-reviewed literature or to any validation of the equation. Incidentally, Equation 5-7 is confusing in the way the "tcn^2" term is written.

Several important references such as the one in the preceding paragraph, the MINTEQ references, the MEXAMS reference, Jacobson et al. (1985), and draft EPA reports are relied upon to explain and justify the methodology. These references have not been peer-reviewed, and their credibility and scientific validity have not been accepted by the professions. We recognize the urgency with which EPA frequently has to prepare documents and methodologies. However, it is less desirable and frequently inappropriate to base approaches and decisions on material and reports that have not been adequately peer reviewed and evaluated.

x. Page 5-10: Middle of page - It is stated that C_v can be determined for the liquid concentration of the contaminant. The logic of how this statement relates to the sludge landfill situation is not clear. Sludge dewatered to 20 to 40% solids is assumed to be placed in the landfills. Thus the contaminants are not likely to be in the liquid phase. No information is provided to justify that C_v values valid for liquids are also valid for contaminants on solids in dewatered sludges. One reference is cited (English, et al., 1980) which presents some evidence that ammonia emission follows Henry's Law, but the title indicates that it applies to surface-applied sludge rather than diffusion though the soil cover of landfilled sludge.

y. Page 5-10: The constant 0.994 (i.e., less than 1.0) in Eq. 5-5 implies that the mass transfer coefficient decreases as temperature increases. This is very unusual. The Committee recommends that this value be checked.

z. Page 5-11 (top): Again it is noted that vapor concentration can be expressed in terms of a liquid concentration. It is not clear that this methodology is appropriate for dewatered sludge landfills.

3. Corrections

a. Page 4-2: In the line above Equation 4-1, a 5-gram sample is indicated. It should be made clear whether this is wet or dry weight.

Below the equation, the sample size of 0.005 is indicated to have the units of grams. This should be checked since it appears that the correct units should be kilograms.

b. Page 4-13: Equation 4-5 is mistyped. The correct version is given on p. 4-14. The report is, in general, difficult to follow because of sloppy equations and notation. For example, R is usually used for retardation coefficient, but appears as recharge on the bottom of p.4-75.

c. Page 4-19: The last sentence of paragraph 3 should read:

"When invalid, this assumption overpredicts contaminant concentrations by underpredicting travel time."

or

"... overpredicting the flow velocity."

but not:

"... overpredicting travel time."

d. Page 4-26: "f" should be used instead of "o" in Equation 4-15, because retardation occurs at "ambient" water conditions, not saturation. This is also true in step G on p. 4-77 where f_{ave} should be used instead of f_s. (Note how the notation keeps changing.)

e. Page 4-32: First full paragraph, second line - Little or no effect on the hydrology of the aquifer, not chemistry.

f. Page 5-11: T_Z in equation 5-11 is undefined.

C. Land Application and Distribution and Marketing

The document is an extensive treatment of a methodology to assess risks associated with land application and distribution and marketing of municipal sewage sludge. Chapter 1 introduces the material to be covered in a general way. Although the methodology presented is generic, a listing of the contaminants for which it is intended should be included. The intent of the document and the audience and intended users should also be clearly stated in the introduction.

The general approach for each sludge disposal/reuse option is to define what is termed the "most exposed individual(s)" (MEI), and to model exposure to such individuals via the various terrestrial food chain, particulate resuspension, surface runoff, groundwater, and vaporization pathways. The output of the model determines the allowable concentration of contaminants in sludge and/or the sludge disposal rate. The most exposed individual varies with each pathway and may be either an animal, plant, human, or soil biota and their predators. The reuse/disposal options include agricultural utilization, forest land utilization, disturbed land reclamation/utilization, and dedicated land disposal. Distribution and marketing of sludge is treated as a special case of land application. Under each of the various sludge disposal/reuse options a number of assumptions and requirements or potential requirements are outlined.

For each terrestrial food chain pathway, a most exposed individual and routes of exposure to the target organism are identified. In terms of possible harmful effects on humans, routes of exposure include (1) sludge to soil to plant to human, (2) sludge to human (direct ingestion), (3) sludge to soil to plant to animal to human, and (4) sludge to animal (by direct ingestion) to human. In terms of possible harmful effects on animals, including wildlife, routes include (1) sludge to soil to plant to animal, (2) sludge to animal (direct ingestion), and (3) sludge to soil to soil biota to animal predator. Routes of exposures, in terms of harmful effects on plants and soil biota, include (1) sludge to soil to plant and (2) sludge to soil to soil biota. Each of the pathways are examined relative to current as well as future land use (e.g., current agricultural use followed by future conversion to residential use).

The methodology used to arrive at the level of exposure and subsequent criteria for limiting sludge contaminant concentration and/or application rate involves the use of a series of equations to estimate exposure concentrations. This level of exposure is then evaluated in terms of its effects on the target organism.

1. General Comments

a. Most Exposed Individual

As discussed earlier, by establishing the most exposed individual (MEI) as the exclusive method of risk assessment analysis (p. 1-4), the methodology steps over the boundary from risk assessment to risk management without establishing a clear perspective on the level of risk that has been chosen. On page 1-3, EPA acknowledges that "the compounding of worst-case assumptions may lead to unrealistic results." It is further indicated that estimates of central tendency should be used as well as upper-limit values. However, in the body of the document, the concept of central tendency is often ignored, whereas upper-limit values, or the more conservative values in the face of poor data, are discussed in great detail. When these upper limits are strung together in the analysis, it is difficult to judge whether the individuals so exposed truly exist. To provide perspective, it is recommended that the risk assessment methodology specifically address more than just the MEI, especially by developing scenarios using median or other central tendency values for the pertinent factors in the analysis. This will also make the document more useful for certain site-specific or regional analyses, where the population exposed is smaller and more easily characterized and where the assumptions used to establish the MEI may be inappropriate.

b. Exposed Population

The risk assessment document provides few insights into the estimated numbers of individuals exposed via a given pathway. It is understandably difficult to do this on a national basis for the various levels of exposure in each pathway. However, it is likely that once this analysis is applied, a few critical pathways will appear as the controlling factors for allowable contaminant levels in sludge or application loadings. At that point, actual numbers of individuals exposed can be estimated.

For example, for distribution and marketing, the "pica" syndrome involving exposure of children to lead may become the controlling factor in assessing risks for lead. The document, however, provides no clue as to how many children are so affected, making it difficult to judge if this is a major or minor problem. Some attempt to quantify the exposed population is necessary if this is to be a credible basis for regulation.

Similarly, the document should reexamine the assumptions for the MEI along certain critical pathways and determine whether a significant portion of the exposed population exists at that risk level. Using the "pica" example again, the authors flatly state (page 4-73) that a body weight of 10 kg should be used, which is the median weight at 12 months of age. A common reaction would be that few people let a 12-month old baby run free on a regular basis where they may ingest soil treated with sludge; there is a need to know how frequently such a situation is estimated to exist.

c. Dedicated Land

The concept of dedicated land is not clearly stated in Chapter 2. No distinction is made between application rates, land use, and crops to be grown and their disposition on a dedicated site versus a drastically disturbed sludge utilization site, such as a reclaimed strip mine. The document should clearly define dedicated land application to distinguish it from other sludge utilization methods.

d. Forest Land

It is incorrect to imply that forest land utilization has an advantage over agricultural use because it lessens human exposure. Exposure could be lessened and not necessarily be harmful to humans, but could adversely affect the forest ecosystem. Harmful effects could occur on forest ecosystems following sludge applications at rates comparable to those not producing harmful effects with agricultural utilization.

Although higher application rates can be used on forest land, it is not necessary to assume that sludge will be applied to forest land at rates higher than agronomic rates. The document suggests that the high storage capacity of litter on the forest floor will prevent nitrate leaching following sludge applications at higher than agronomic rates. The storage capacity of the litter may serve to lessen, but will not prevent nitrate leaching.

e. Assumptions

The methodology assumes that trace metals are conserved indefinitely in the upper layer unless loss constants are available. Available data show that a number of contaminants considered to be trace metals are lost by volatilization and/or leaching. (Since the term trace metal means different things to different people, the report should define this term.) Trace elements lost by volatilization may include mercury, selenium, arsenic, and probably others. Boron, arsenic, and selenium (particularly in the selenate form) are easily leached to groundwater. This assumption should be deleted or revised to point out exceptions.

In terms of toxicity thresholds for non-human organisms, it is incorrect to assume that "all inhibitory effects" are adverse. Many routine agricultural management practices, such as fertilization, will at least temporarily inhibit microbial activity.

The document indicates that plant uptake response, when expressed as a function of cumulative contaminant application, is curvilinear, and approaches a horizontal asymptote (plateau). It also states that field data should be used to arrive at the plateau concentration of contaminant. Although the available data base is sufficiently complete to arrive at a plateau concentration for a few crops, the Committee does not believe that data are available for a wide variety of food chain crops. The document further assumes that the response of any crop across a wide variety of soils and sludges can be expressed in terms of any other crop. This assumption may not be valid. Its use in the methodology should be justified using field data.

f. Methodology

The document should provide some information on how levels for total background input (TBI) from all other sources (food, water, air, and others) will be obtained. The rationale used to arrive at the relative effectiveness (RE) of the exposure routes needs to be stated.

The zone of sludge incorporation is 20 cm, not 15 cm as indicated on page 4-5. We recommend that the incorporation depths for sludge be changed to 20 cm in keeping with standard agricultural practice.

The derivation of the fraction consumed (FC) factor in Table 4-12 is unrealistic. Section 4.2.3.1.1 states that direct human consumables are less than non-direct human consumables, so the 5 percent value stated in Table 4-12 should have been <2.5 percent based on this information alone. This value should be further revised downward (to less than 1 percent) because realistically very few commercial food producers will depend on sludge fertilization when commercial inorganic fertilizers will result in higher yields, fewer regulatory constraints, and easier application.

The FC values in Table 4-12 for the home garden exposure scenario seem very high, especially since this scenario is for a rural garden, a situation where it is unlikely that sludge would be used. These values should be reviewed and revised as appropriate, using the most recent information available from the U.S. Department of Agriculture.

Soil ingestion (Section 4.3.3.1) has to be considered a very minor pathway. In addition, since the ingestion rate studies have produced inconclusive data, further studies should be done before any soil ingestion rate is included in this document.

For inorganics, the methodology used to determine the reference sludge concentration (RSC) not causing the reference tissue concentration (RTC) to be exceeded (pages 4-40 to 4-59) is reasonably straightforward. However, the success of the methodology in terms of establishing realistic criteria depends very much on the accuracy of the parameters which go into the equations. One needs to know the curvilinear relative response values for a number of food crops, the relative uptake response values for each food crop, the relative tissue concentration for the index crop, and plateau values for the index crop (Table 4-7, page 4-42). We support the curvilinear response concept. However, the available data base requires selectivity in its use. The document should provide assurance that, when this concept is applied, there are sufficient data to justify its application. We believe that the usefulness of the document will be enhanced if actual rather than hypothetical data were used in the examples presented.

To evaluate the sensitivity of the model, the Committee undertook its own analysis, using actual, rather than hypothetical, data. The results of this analysis are presented in Appendix E of this review. In general, the results show that the model is quite sensitive to the selection of the values for the daily allowable dietary intake from sludge-fertilized crops (RIA) and the fraction of diet from such crops (FC). The model is also greatly dependent on the curve fit selected to obtain tissue concentration plateau values (P). Based on this analysis, the Committee recommends that the model be used for regulatory purposes only when realistic, reasonable values for such parameters are available.

g. Inhaled Particles and Surface Runoff

Chapters 5 and 6 are well written and to the point. This section of the document provides technically sound guidance with proper caveats to indicate inevitable weaknesses and uncertainties which remain in any method of this sort.

The Committee notes that the document does not contain discussion and evaluation of the inhalation of aerosols as an exposure pathway. We believe that for the sake of completeness, and to clarify that this pathway has not simply been omitted inadvertently, some statement should be added. The following is suggested:

> The use of anaerobically digested municipal sludge as a fertilizer and/or soil amendment has become a widely accepted method of sludge disposal in the United States. Despite the extensive processing which sludge undergoes prior to ultimate disposal on land, the possibility of increased viral and bacterial concentrations in the environment near sludge application sites has remained a concern. In particular, the possibility

of health risks associated with public and/or occupational exposure to microbial aerosols generated during the sludge application process has received considerable attention. This is especially important when some form of spray application is being employed.

Enteric bacteria and viruses are present in the raw sewage entering the wastewater treatment facilities (11). A portion of these become adsorbed to the sludge solids as they pass through the treatment process. Dudly et al. (12) have enumerated over 20 genera of bacteria present in anaerobically digested sludge, and Berg (13) and Sagik at al. (14) have isolated enteric viruses from anaerobically digested sludge.

The Metropolitan Sanitary District of Greater Chicago conducted an aerosol sampling program at its Fulton County (Illinois) land reclamation site (15), as part of a larger, EPA-funded environmental monitoring program. Aerosol samples were collected upwind and downwind of various spray application sites using Litton high-volume samplers and Andersen six-stage viable impactor samplers. The Litton samplers indicated bacterial concentrations of 10^4 to 10^6 colony forming units (cfu) per cubic meter of air at distances of 50 to 450 meters downwind of the sprayers, compared to bacterial concentrations of 10^2 cfu/m^3 air upwind of the sprayers. The Andersen samplers indicated bacterial concentrations of 10^1 to 10^3 cfu/m^3 air at varying distances downwind versus 10^1 to 10^2 cfu/m^3 air upwind. Of all the air samples collected, one upwind and three downwind samples contained a combined total of six poliovirus type 1 plaques.

Sorber et al. (16) conducted a microbial aerosol sampling study of four sludge application sites. Two sites used sludge application from trucks; two were spray application sites. Analysis of the sludge prior to application indicated the presence of a variety of bacterial genera, as well as enteroviruses. Aerosol samples were collected using high-volume air samplers. Results at the truck sites indicated elevated levels of standard plate count and fecal streptococci 50 to 100 meters downwind of the sludge application area. Results at the spray application sites indicated elevated levels of total coliform, fecal coliform, and fecal streptococci 50 meters downwind of the spray nozzles. Six aerosol sampling runs for viruses were conducted, and no human enteric viruses were detected in any aerosol samples. This represented a theoretical aerosol concentration of less than 0.0016 plaque forming units per cubic meter air, based on the detection limits of the analytical system used.

Results of the above two studies, as well as studies concerning aerosols generated from wastewater aeration (17) and spray irrigation (18), have demonstrated no adverse impacts of microbial aerosols on human health.

The methodology for computing inhaled particulates in Chapter 5 is reasonable, though Gaussian puff models are rarely applied on such a small spatial scale. The resulting concentration of particulate matter computed above the field during tillage (33 mg/m^3) is at the high end of the range of concentrations reasonable for dusty, outdoor work environments, but is possible. The remaining step in selecting the pollutant-to-solids ratio for the sludge-amended soil is straightforward.

The runoff exposure methodology in Chapter 6 is long, but easy to follow. The models presented are at an appropriate level of complexity for an analysis of this type. The tiered approach is sensible.

Most of the equations in Chapters 5 and 6 have been checked and they appear to be correct. There was some question raised by Environmental Criteria and Assessment Office (ECAO) reviewers, however, as to the origin of Eq. 6-8. It is the correct solution for the average value of available mass, as indicated in the text.

The report includes a good discussion of the effect of sludge amendment on the physical properties of soils pertinent to runoff generation. Additional discussion and guidance is required for a key parameter in the model: the adsorption partition coefficient, K_d. Apparently, the report relies upon the landfill groundwater section to provide this information, but discussion and reference are required here as well.

The Universal Soil Loss Equation (USLE) and Modified Universal Soil Loss Equation (MUSLE) mathematical models are used to predict soil loss from sludge-amended fields. A sediment delivery ratio is then used to determine the potential for introduction of soil to aquatic systems. The USLE and MUSLE models are designed to predict movement within a field, as opposed to movement to the edge of a field. To use the soil loss information predicted by these two models would result in a gross overestimate of soil movement to the edge of a field.

Since there are several established models currently being used to predict soil movement to the edge of a field, EPA should use one of these more appropriate models. The U.S. Department of Agriculture Soil Conservation Service has been using the CREAMS model (19) extensively for this purpose. The Office of Surface Mining has recommended the use of SEDIMOT II (20) for disturbed lands, and this model has been adopted for such use by a number of states. Both CREAMS and SEDIMOT II produce, as part of their output, distributions of soil particle sizes. This is extremely useful in evaluating the characteristics of the exported soil material which leaves the field-scale area and enters the surface waters. This provides the user with important water quality insights, such as the proportion of various particle-size classes, including small particles on which pollutants could be adsorbed. (Within the past year, an improved model based on SEDIMOT II called SEDCAD Plus (Sediment, Erosion, and Discharge by Computer Aided Design) has been released (21).)

In light of these comments, we recommend that the Agency consider the use of CREAMS and SEDIMOT II.

One area that remains poorly resolved is the probability of occurrence of the design instream concentration used in the methodology. The report states that a 1-in-5-year runoff load together with a 1-in-5-year dilution flow yields a 1-in-25-year instream concentration, so long as the load and dilution flow are independent. (It further notes that correlation between the load and dilution flow is such that the actual return period is longer, i.e., the probability of occurrence is lower.) The original assertion is incorrect, however, even if runoff loads and dilution flows are independent.

To illustrate that the assertion is incorrect, assume the following notation:

M = runoff load
M^* = 1-in-5-year runoff load
V = dilution volume
V^* = 1-in-5-year dilution volume
C = instream concentration = M/V
P = annual exceedance probability = 1/return period

Thus,

$$P\ (M > M^*) = 0.20$$

$$P\ (V < V^*) = 0.20$$

While it is true that, if M and V are independent:

$$\begin{aligned} P\ (M > M^* \text{ and } V < V^*) &= P\ (M > M^*) \cdot P\ (V < V^*) \\ &= 0.2 \cdot 0.2 \\ &= 0.04 \end{aligned}$$

It is not true that:

$$P\ \left(C > \frac{M^*}{V^*}\right) = P\ (M > M^*) \cdot P\ (V < V^*)$$

For example, say $M^* = 50$ and $V^* = 10$ then the proposed $C = 50/10 = 5$. But we do not require $M > 50$ and $V < 10$ for C to be > 5. We could have $M > 40$ and $V < 8$ and still get $C > 5$. As such, $P\ (C > 5)$ is actually larger than 0.04, and the corresponding return period is less than 25 years (again, assuming independence).

The proper treatment involves a convolution integral for quotients of random variables, and requires knowledge of the distribution functions for M and V. The procedure is outlined in Benjamin and Cornell (22). Unfortunately, it is difficult to implement, especially when M and V are correlated. The following alternative approaches to this problem should be considered:

1). Use continuous rainfall-runoff simulation for the entire watershed. This inherently accounts for correlations between runoff load and flow rate and properly computes the exceedance probability of C. The drawback is in the expense of long-term simulation, but the option may be appropriate for analysts experienced in watershed simulation.

2). Apply the approximate analytical method of Di Toro (23) which assumes that runoff load and dilution flow are lognormally distributed, and allows for correlation. This method was developed for the EPA National Urban Runoff Program (NURP). A discussion of the applicability and limitations of the approach is presented in an SAB review of the methodology (24).

3). Dictate that the design condition be defined by a 1-in-5-year runoff load and a 1-in-5-year dilution flow, but make no inferences whatsoever concerning the return period of the resulting instream concentration.

h. Ground Water Exposure Pathway

The methodology for the ground water pathway in this document is essentially the same as the procedure for the landfilling option, with the exception of some differences in the specification of the source term. The comments in the landfilling section (III.B.) are thus generally applicable to this section; however, the following distinctions are noted:

- Chemical conditions likely to prevail below a land application facility are likely to differ from those below a landfill. In particular, aerobic conditions are more likely to occur below a land application facility (depending on loading rate and operating conditions). Therefore, in land application, nitrification of ammonia is likely, and biodegredation rates determined for aerobic conditions are appropriate.

- The relative importance of the ground water pathway in land application and landfill options may be different, as may be the relative importance of other pathways.

Section 7.3.1 describes the use of TCLP procedure to predict leachate concentrations from sludge-soil mixtures. The TCLP test was designed to simulate leaching of mixed wastes in landfills. The procedure has not been validated for use on sewage sludges, nor for simulating leaching from land application. In addition, the spiking tests are not reasonable. The TCLP test was designed to predict the acutal leachate concentrations to be expected. TCLP test results should be regarded as the final input parameter, not results from artifical spiking tests. As stated in Section 4.1.2.1.1, "Studies using metal salts, added either to soil or a sludge-soil mixture, also tend to over-predict field responses."

i. Vaporization

Section 8.3 described the calculation for vapor concentrations of volatile contaminants from land applied sludge. The tier 1 calculation using Henry's Law, incorporates only the Henry Law constant and partial pressure in the analysis, and ignores soil sorption and biodegradation which would signficantly reduce the amount volatilized. The tier 1 equations should therefore include appropriate coefficients to reflect these factors.

Section 8.4.3.1.4 states that the MEI for volatile organics from land receiving sludge inhales 100 percent of his air from the sludge-applied area. Since the MEI for this pathway considers only humans, it is unrealistic to expect the MEI to spend 100 percent of his/her time in one spot. Further, the vapor phase concentration should be reduced as suggested above prior to applying the tier 2/3 equation for dispersion and the consequent exposure to the (human) MEI based on the worst case residence time. Further review of the vaporization pathway methodology is included in the landfill section (III.B.), and those comments are applicable here, as well.

j. References

Every effort should be made to cite only references which can be retrieved. Examples of references which are difficult to retrieve or improperly cited follow:

p. 9-1: Binder, S., D. Sokal, and D. Maughan, 1985; Birkbeck, J. A. 1977.
p. 9-2: Booz-Allen and Hamilton, 1982.
p. 9-3: Chaney, R. L.., J. C. Smith, Jr., D. F. Baker, R. J. F. Bruins and D. Cole, 1986.
p. 9-4: Environmental Science and Engineering. 1985.
p. 9-5: Flynn, M. P. 1981; Fruhman, G. 1964.
p. 9-7: Loma Linda University, 1978.
p. 9-8: NRC (National Research Council). 1980.
p. 9-10: Society of Actuaries. 1959.; Stephen, C. E. 1980.

2. Specific Comments

a. Page 1-1, Line 2: As discussed earlier, since the methodology applies to effects on plants, animals, and humans, the Committee suggests use of the term "Most Exposed Unit (MEU)."

b. Page 1-3, Lines 22-24: Although the key to effective use of the methodology is a careful and systematic examination of effects of varying input parameters, such sensitivity analysis is not presented in the document.

c. Page 1-4, Line 24: Although the text states that quantities and kinds of food consumed by humans (MEIs) are not given, they appear in the appendix.

d. Page 2-1 (and throughout the document): The IS designation for metric ton (Mg) should not be used. Dry weight (DW) should be defined in terms of method of drying and temperature. The terms "pollutant" and "contaminant" are used interchangeably throughout the document. Either one or the other should be consistently used.

e. Page 3-3, Table 3-1: This table should be either simplified or deleted. In its present form it is difficult to follow. The information presented in the table is repeated in the text. The designation of application pathways to current as well as future use is somewhat arbitrary and, probably because of this, is not internally consistent throughout the table. For example, under suggested categories for all land application practices except dedicated land disposal, all exposure pathways are considered to be applicable to current, as well as future use, yet examination of the matrix under the specific land application practice indicates a number of pathways to be applicable to only current or only future use. For example, under agricultural use Pathways 3 through 13 are designated applicable to only current use. Under forest use: Particulate resuspension, surface runoff, and groundwater are as likely a future pathway as is sludge-animal (direct ingestion). Footnote C: Future use may be of concern, but not necessarily of greater concern than current use.

f. Page 3-5, Lines 1-3: In the crops for human consumption pathway, the document states that risk is assessed on the basis of eventual suitability for home gardening. If this is the case, evaluation of risk associated with agricultural use is irrelevant.

g. Pages 4-2 and 4-3, Table 4.1: "Assumptions" could say the 15 cm soil layer with a dry mass of $2x10^3$ Mg/ha is one with a bulk density of 1.33 g/cm^3 or a silt loam texture.

Under contaminant loss from soil - Trace metals: Trace metals should be defined. Available data demonstrate that trace metals are not conserved indefinitely. A number including Hg, Se, B, and As are lost by leaching and/or volatilization. Metals leave the site through the resuspension and tillage operations.

h. Page 4-3: With respect to toxicity thresholds. Considering all inhibitory effects as adverse is a poor assumption since almost anything one does to a soil causes an inhibition (at least temporary) of biota.

i. Page 4-3: The document does not support the use of the 25-30 year old male as the MEI.

j. Page 4-5, Line 18: It is incorrect to assume that inorganic contaminants are conserved indefinitely in the upper layer.

k. Page 4-9: A specific value or range of values should be given for land use conversion period (T).

l. Page 4-12: A brief explanation of the plateau hypothesis should be provided.

m. Page 4-18, Line 6: Add that the phytotoxicity limit is dependent upon a number of soil and sludge factors, and that it will vary over a large range.

n. Page 4-22: Under (1): Reductions in soil microbial activity should not be considered adverse since they occur following a number of agricultural management practices such as when agricultural chemicals are used. A procedure to assess toxicity to soil biota (except plants) seems difficult if not impossible to work out. Many operations adversely affect organisms, but the organism concentrations usually rapidly return to their original state. Thresholds for predators of soil biota would seem to be even more difficult to determine. A 5 percent reduction in the yield of crops is most difficult to determine, and is well within the margin of error.

o. Page 4-40, Step A: The validity of using relative response values should be confirmed before incorporating them into the risk methodology. The data base at present is probably not adequate to test this concept for a wide variety of crops.

p. Page 4-41, Table 4-6: The assumption that the response of crops in a given food group can be represented by a single value may not be valid and needs justification. Data from a 1966 survey for the percent of homegrown food in the diet may not be representative of present-day practices. More recent data should be obtained and used in the methodology.

q. Page 4-43: Some justification in terms of computations from available published information should be provided to establish the validity for the use of equation 4-18. The sensitivity of the relative response concept could be tested using existing data. For example, using actual data, the uptake of crop A relative to the index crop I (RU_{A1}) can be cross checked using actual data and the procedures described to develop equations 4-18 and 4-19. The procedure involves determination of the relative uptake of crop A (RU_{IA}) and crop B (RU_{B1}) to an index crop I, then determining the uptake of crop A to crop B. With the data one can determine RU_{AI} from two independent measurements and thereby obtain an indication of the validity of the relative uptake concept.

r. Page 4-43: Some data to justify assigning a single relative response value for food groups (e.g., grains and cereals) should be provided. A sensitivity analysis regarding this procedure should be performed. Weighting relative to foods within a group which make up a substantial part of the diet should be considered.

s. Page 4-44: The methodology for substitution of food uptake values is incorrect. The document indicates that, if no relative response value can be determined for a particular food group, then the highest value of the other known food groups should be used. We recommend that an uptake value for a food group most similar to the food group for which data are not available be used when substitution becomes necessary.

t. Pages 4-44, 4-45: In Step C, a value for the reference tissue concentration for an index food group, not an index food crop, is being determined.

u. Page 4-46: The document states that it is highly unlikely that a person could be exposed, year after year, to crops grown immediately after a first sludge application. There is no need to use data from crops grown immediately after a first sludge application, because provisions have been made in the document for substitutions of similar food groups.

v. Page 4-49, Table 4-8: It is not clear what the difference is between columns labeled ">6.0 and/or <6.0" and "<6.0 only" in the first column heading. It would seem that the "no pH requirement" for the Reference Sludge Concentration (RSC) based upon its determination from studies with pH <6 may not be adequate to insure that the tissue concentration will be less than the tissue concentration not be be exceeded (RTC). For example, if the studies on which the RSC were based were made at pH 5.5 and the sludge application caused the pH to drop to 4.5, the RTC very well could be exceeded.

w. Page 4-50: The basis for an annual contaminant limit of 0.1 kg/ha should be provided. Also, if an application of 10 Mg/ha over several years did not cause the RTC to be exceeded, it should not then be necessary to limit a single application to 10 Mg/ha (and possibly lower than the amounts needed to supply N or P).

x. Page 4-52: Step B should provide data to justify that relative uptake response values are sufficiently uniform to be used in a risk assessment methodology approach. With reference to Step E, pot studies provide information not representative of field studies, and should not be used in the methodology.

y. Page 4-54: A concentration in a crop above which crop production is virtually eliminated (TL) cannot be determined with any degree of certainty. Concentrations of metals in crops are very much dependent upon both the synergistic and antagonistic effects of metals in soils. The interactive effects of metals on the metal in question will influence the concentration in the crop associated with phytotoxicity.

z. Page 4-57: With reference to Step B, can uptake response slope for food groups be established from the data for slopes from food crops?

aa. Page 4-59: With reference to Step D. Reference application rates of sludge for phytotoxic effects of trace elements cannot be determined and are not available, at this time.

bb. Pages 4-61 to 4-66: The data presented in Table 4-12 (page 4-62) on the fraction of the human diet originating from sludge-treated soils is incorrect for both agricultural and home garden use. The data given is for a worst-case scenario which could never occur. For agricultural use, we recommend that the fraction of the human diet originating from sludge utilization be the product of the fraction of the total land in the United states that is sludge amended (0.02) and the fraction of sludge-grown crops estimated to be marketed for human consumption (less than 0.10). The document states that home-grown foods constitute about six percent of the food consumed in all households in the United States. That fraction (0.06) times the fraction of sludge-amended lands in the United States (0.02) should be used as the fraction of the human diet from sludge-amended home gardens; i.e., 0.06 x 0.02 = 0.001.

cc. Page 4-65: The value of 5% of the food in the diet derived from sludged lands is too high. We recommend that an analysis of current and projected practices be conducted and a more realistic value obtained and used. Likewise, values for FC for home gardeners of 0.60 for vegetables, 0.45 for potatoes, and 0.17 for dried legumes seem high. Some foods (e.g. potatoes) constitute a major part of the U.S. diet, and it may be advisable to instruct home gardeners not to raise potatoes on lands that have received sludge.

dd. Pages 4-75 to 4-84: The fraction of the meat food group assumed to be derived from sludge-amended feedstuffs in Table 4-18 is too high. We recommend that this number be the product of the fraction of the population growing their own (0.06), the fraction of sludge-amended land in the United States (0.02), and the fraction of the meat food group given in Table 4-18 (0.23 to 0.48). Range (0.06 x 0.02)(0.34) to (0.06)(0.02)(0.48) = 0.0004 to 0.0006.

ee. Page 4-78: If equation 4.30 applies to all animal feed, this should be stated in the text.

ff. Page 4-84: Threshold feed concentrations (TAs) may be reasonably well known for domestic farm animals, but values for wildlife may be difficult to come by. Also, TAs usually are determined by total diet.

gg. Page 4-85: The TP phytoxicity threshold may be difficult to determine because of interactive effects. Selection of most sensitive plant species may be inappropriate since the species may not grow in the area in question.

hh. Pages 4-86 to 4-89: The exposure pathway for soil biota and their predators is not demonstrated in the document. There are meager data given to assess this pathway. It is unreasonable to limit sewage sludge application because of possible predator toxicity without further evidence. We recommend that the validity of this pathway be reassessed through a more thorough examination of the scientific literature. If further evidence of the significance of this pathway cannot be found, it should be eliminated.

ii. Page 4-86: The soil biota toxicity as a pathway may not be a valid approach. Reduction in soil microbial activity and diversity as an adverse effect is not a logical procedure to follow.

jj. Page 4-88: Uptake response curves for soil biota (UB) are scarce. Likewise, (TA) threshold concentrations for the predators and (BB) background concentrations in soil biota are not well established.

kk. Page 4-90: Although the calculations presented in Section 4.8 are examples of model output, when testing the sensitivity of the methodology, actual data (from as comprehensive sources as are available) should be used in the example calculations.

ll. Page 4-93: With reference to Steps D and E, rather than using hypothetical data for the determination of plateau values for the index crop, actual data from the literature should be used. Example calculations are presented for first-year data, while the methodology recommends against using first-year. We recommend that first-year data not be used in example calculations.

mm. Page 4-97: Equation 4-24 is quite sensitive to the value chosen for TL_i (maximum concentration) of crop "i" above which crop production is virtually eliminated by phytotoxicity. As mentioned previously, values for TL_i probably vary substantially for different sludges and soils. Adjustments for phytotoxicity (eq. 4-25), therefore, are probably not possible.

oo. Page 7-11: The document indicates that the applicant can spike sewage sludge with increasing levels of a contaminant so as to determine maximum solubility levels for leaching. This procedure of artificial spiking is similar to previous attempts to add metal salts to sludges so as to assess the crop response to higher metal concentrations. This has been shown to lead to an over prediction of crop metal response as compared to actual field conditions because the metal salts were more soluble and available for crop uptake. The artificial spiking of sewage sludge also will result in an over prediction of the leaching response. We recommend that application of the methodology based on artificial spiking of sewage sludges be eliminated.

pp. Pages 8-1 to 8-6: The document describes a method for calculating vapor emissions of volatile organics from sludge-applied land. However, this methodology makes no provision for soil sorption or biodegradation of the volatile organics, two important reactions that contribute substantially to lower emission rates. The equations for tier two and three should be revised to reflect these important factors.

qq. Page A4-18 (Appendix associated with Chapter 6): The symbol "D" is used both for watershed dilution and the dispersion coefficient. This is confusing. Also, it is surprising that the dispersion coefficient does not appear in Eqs. A4-28 and A4-31, since dispersion spreads out the storm pulse, as indicated in Figure A4-5.

3. Corrections

a. Page 1-1, Line 12: Insert "adverse" between "for" and "health."

b. Page 1-1, Line 24: Change "humans" to "target organism."

c. Page 1-3, Line 14: After "human health" insert "and the environment."

d. Page 3-6, Line 15: Grains are not considered to be row crops.

e. Page 4-6, Line 9 (and elsewhere): There is no need to specify base to the natural logarithm to six significant figures.

f. Page 4-7: For clarity may be desirable to change symbols for either LC_1 or LC_1'.

g. Page 4-8, Equation 4-11: e_{-k} should be on same line as D. It appears as a subscript in eq. 4-11.

h. Page 4-9, Section 4.1.1.3.2: The symbol "n" is used to designate time (years) as well as number of annual application rates. The symbols n, t, and T appear to be used interchangeably. This section is confusing and should be clarified.

i. Page 4-10, Section 4.1.1.3.4: Nitric-perchloric acid will only approximate total metal concentration.

j. Page 4-36, Line 11: After "compounds" insert "of elements."

k. Page 4-45: Under Step D, Line 13, "paste" should read "suspension."

l. Page 4-56, Table 4-10: We believe that ">6.0 and/or <6.0" should read ">6.0 and <6.0."

m. Page A4-6 (Appendix associated with Chapter 6): In the last line of Section A4.2 replace "low" with "high."

D. Incineration

Incineration represents one means of disposal that many cities have adopted in practice. The method reduces sludge organic content substantially, but at the same time concentrates certain metals in scrubber water or bottom ash. The method also introduces a potential for exposure to air pollution from gaseous and particulate combustion residues.

1. General Comments on the Methodology

The document, "Development of Risk Assessment Methodology for Municipal Sludge Incineration," is a major step toward providing a guideline methodology for health risks associated with the current practice of incineration.

The document, however, assumes that the solid (ash) and liquid side streams from the incineration process are treated. The efficacy of treatment should be explicity discussed. For example, the recycling of contaminated scrubber liquor is part of normal operations. If the ash is hazardous, it could be disposed of under RCRA regulations. The disposal, however, has an accompanying risk that should be incorporated in the discussions.

Allowing the use of site-specific, local data in place of national standards makes for more rational permitting considerations and should be encouraged. The Science Advisory Board Environmental Engineering Committee has advocated such an approach in several past reviews (25).

2. Specific Comments

a. The discussion or overview for the guidelines to prepare a comparative analysis for estimating risks from different disposal techniques for solid and liquid waste streams is not satisfactory for the following reasons:

1). The groundwater pathways and POTW pathways for the scrubber water, discussed in "Chapter 3, Identification of Key Pathways," are not as detailed as comparable discussions in the other municipal sludge risk assessment methodology reports. Thus there is inconsistency in scope among the methodologies. Chapter 3 does not discuss the ground water pathway even though it is indicated to be a key component of the pathways described in Figure 3-1. It is assumed that most incinerator ash will be nonhazardous under RCRA criteria. This may not always be the case using new toxicity characteristic leaching procedure (TCLP); however, a recent study by Environment Canada (26) does suggest that ash from sewage sludge incinerators is "benign," with most of the metals speciated into insoluble oxides and silicates.

Scrubber water (pg 3-7) is assumed to be diluted or well dispersed when recycled to the front end of a POTW. Such recycling is common but does not guarantee that dilution of the scrubber liquor will yield no adverse impact on POTW sludge quality or on POTW performance. The document is unclear on such possibilities.

We suggest that a review of National Pollution Discharge Elimination System (NPDES) permits for existing treatment plants with and without incinerators using scrubbers would be helpful in clearing up the question of scrubber liquor discharges.

2). The evaluation of incineration risks also excludes without justification other releases including transportation accidents and spills, and fugitive emissions. The document must justify excluding these sources, or must evaluate them explicity.

3). The Most Exposed Individual (MEI) concept needs to be examined as applied to incineration. Are short-term exposures important to consider? Does the maximum annual ground incineration exposure occur due to downwash very close to the incinerator where people do not reside? The regulatory considerations of "fence-line" limitation should apply here.

The use of MEI will only estimate effects on one hypothetical human individual; and the effects over groups of individuals or over generations of individuals cannot be determined. The use of the proposed MEI concept (focusing on humans) perhaps erroneously tends to skew the end results toward options where direct human exposure is minimal. To illustrate the problem with the proposed MEI concept, one chould carry the risk assessment evaluation one step further to evaluate risks to the human MEI from incineration of sludge at sea. Although costly and not presently practiced, incineration at sea may be the safest alternative if the present (human) MEI criteria are to be met. However, the proposed MEI approach does not account for acute exposure to humans or to other biota exposure, thus oversimplifying the risk expected. The present approach is not acceptable.

The selection of the MEI as a chronic effect over a 70-year event may not be typical of those most in need of immediate relief from air contamination. Sensitive individuals such as infants may be exposed to lead or mercury in short-term transients. The assumption that the MEI is exposed outdoors for 70 years needs to be examined in the light of potential short-term exposure.

The cumulative probability of the MEI exposure should be developed. In particular, multiplicative probability needs formulation to account for a) scrubber and sludge metal concentration, b) air emissions, and c) multimedia transport and assumed exposure for the specified duration. Without considering such a cumulative probability, the risk model cannot apply to estimating long-term insults to the environment.

4). There is no discussion of other aspects of environmental exposure included in the methodology (e.g. materials, vegetation, or wildlife). This is needed to permit a comparative study with other disposal/reuse options.

b. Air Emissions.

The crux of the risk assessment depends on knowledge of air emissions from incinerators. These do not appear to be well characterized in past studies available for this report, especially for non-steady operating conditions. A range of emissions of metals and gases or organic vapors has been summarized in a recent report (27). The document should reference this report and give critical comments on the emission data limitations. The significance of non-steady or upset conditions should be discussed. The authors may want to add caveats about on-going research in this area. At a minimum, a sample of incinerator records should be examined to determine a frequency of occurrence of upset conditions. From such data, an estimate of the significance of such conditions, with accompanying emissions variability, should emerge.

There is a lack of reliable data with respect to organic and inorganic emissions from sewage sludge incinerators. This matter should be addressed.

Incinerator air emissions (particulate) are selected as the critical pathway for human health exposure. This is consistent with the findings from the other incineration studies (municipal and industrial wastes). In discussing efficiency of the various pollution control devices, the report correctly points out that "Because the particle size distribution and total loading is so variable between different plants ... the patterns in the data become confused." In too many studies, particle size distribution has been ignored. Particle size distribution is as important or more important than ash loading in the design and evaluation of pollution control devices. Combustion tends to generate sub-micrometer particles which are difficult to control.

The Agency should provide a technical rationale for application of the particulate emission limit. This is especially a concern for sub-micrometer particles since they are very difficult to remove.

The existence (or absence) of afterburners in multiple hearth incinerators seems to be a critical aspect of any design standard or testing program; the report states only that "some" have afterburners. The Radian report (27) relates emissions to various control devices, but not to particle size distribution. Also, the type of afterburner needs to be specified, e.g., is it a converted top hearth, or a specifically designed unit?

Carbon monoxide (CO) should be added to the array of continuous operating monitors. It reportedly is a good monitor of operating efficiency and of organic destruction efficiency when the temperature is high (above 1200° C) and the CO is low (100-400 ppm). Incidentally, the converse is not always true, as higher CO concentrations (especially spikes) can give false negatives.

Although stack heights are presently at the level of structures in the area, there is nothing to preclude building high stacks and using air dispersion, just as water dispersion is considered as an answer to the scrubber water problem. Test cases using only present day combustion systems, stack height, and exit gas velocity may be inadequate. Therefore an expression to take tall stack dispersion into account should also be introduced into the risk model to evaluate alternatives, since the results of dispersion modeling are sensitive to the height-exit velocity-gas temperature parameters.

c. Modeling Methods.

The methods used for modeling dispersion of pollutants are standard approaches endorsed by the Office of Air Quality Planning & Standards. More sophisticated approaches do not seem warranted in the stated approach.

Publication of models to assess risks from alternative technologies should be accompanied by strong cautionary language which points out that the models have not been fully verified in the field. Indeed, representative field data are not available for testing and applying the models, especially for such variable fuel technologies as incineration.

The review of the methodology for the air emissions pathway indicates that the modeling assumes that the incinerators were operating under steady-state, good performance conditions. Important environmental concerns arise when the incinerators are not operated properly and during start up and shut down.

Under these conditions air emissions can be greater, ash quality is not as good (i.e., may contain incompletely combusted constituents), and scrubber water may have more contaminants. The Agency should perform and present at least a crude sensitivity analysis to determine the significance of non-steady-state conditions. (EPA advises the Committee that such work is in progress, and will address acute conditions.)

Most ambient impact studies have dealt with the combination of coal and oil (fossil fuels) for which health effects normally result from long term exposure, as contrasted to toxic substances, where a high emission rate could result in a significant health problem from a single off-design operation. The risk assessment methodology for incineration is primarily based upon a uniform feed rate and a steady state operation, therefore, a response for off-design operations or system failures related to normal emission rates should be considered. This same concern was expressed by the SAB in its report on hazardous waste incineration (28).

The concentrations of key species which comprise the sewage sludge input to the incinerator are not continuously monitored. Thus, it is possible that compounds which would ordinarily be included in the development of emissions rates may not be detected if they are derived from intermittent, rather than continuous feeds. The potential for this type of situation to occur is considerably increased if industrial waste water is included in the sewage. The document does not adequately address these concerns.

Assuming that the steady state condition is adequate, Industrial Source Complex-Long Term (ISCLT) Model is probably the best available Gaussian model for simple terrain locations. It is generally believed to be conservative.

The SAB is concerned that LONGZ excessively overpredicts concentrations at receptor locations above stack height, and its use in certain situations, such as in rough terrain, should be reevaluated.

COMPLEX I is listed in the "EPA Guideline on Air Quality Models" (29) as a screening model. The guideline states there is no acceptable model for complex terrain. COMPLEX II, which is very similar to COMPLEX I, has substantially overpredicted levels measured by monitoring devices. COMPLEX I is probably the best screening model presently available for complex terrain. However, ORD research should lead to major model improvements in the near future for rough terrain applications. The rough terrain modeling potentially is an important area for industrial operations, so that improvements over COMPLEX I and II should be considered as soon as they are available.

E. Ocean Disposal

This methodology is directed to the specific analysis of the 106-Mile site used by the New York metropolitan area. The methodology should be applicable, however, to other deep-water sites. The analysis presented consists of a calculation of the spatial distribution of a potential toxic substance in the surface layer of the ocean, the potential for aquatic toxicity, and a risk assessment for humans based on consumption of fish contaminated by passage through the zone affected by the sludge discharge.

1. General Comments on the Methodology

a. The spatial distribution of the toxic substances at the discharge site is determined in two steps:

1). The determination of concentration in the immediate mixing zone of the discharged sludge serves as a boundary condition for the far-field calculation. The mixing zone is limited to the surface layer, bounded by a pycnocline in the vertical, of an order of a few hundred meters in the horizontal plane.

2). The far-field calculation is based on a two-dimensional advective/dispersive model, which is vertically integrated. Settling is not included and thus, the entire mass is contained in the surface layer. Steady-state contours of concentrations are thereby determined, which provides the basis for the contamination by passage of fish through the field.

b. The framework of analysis is logically structured and the procedure and sequence of steps are sound. Realistic values of mass inputs are known, as well as the geophysical characteristics of the discharge site. Limited field measurements of velocities and trajectories permit at least an order of magnitude assignment of advective and dispersive coefficients for the transport component of the model. The kinetic and transfer elements are not included, which yields conservative results.

A major difficulty facing the authors of the document is the minimal data available, and the lack of calibration and validation of such models. As indicated in the document, in the context of these limitations the approach used by EPA is a preliminary approximation which should provide some basis for analysis. Research underway may provide for more realistic and accurate analysis in the future.

c. No evaluations are made of the potential impacts on humans or aquatic organisms due to spills or releases during loading and transport of sludge on barges. Because this transport occurs through some of the busiest shipping lanes in the U. S., and in an area with highly variable weather conditions, the potential for spills must be realistically evaluated.

2. Specific Comments

a. Modeling and Assumptions

1). A more realistic analysis of the initial mixing zone should be made. A type of modeling framework is presently available (see, for example, reference 30) and may be modified to perform this analysis.

2). While the use of the two-dimensional advective-dispersive approach for the far field calculation is reasonable, a hydrodynamic model of this coastal zone has been developed (31) which would provide a better basis for the transport field. Investigation of its appropriateness to this problem should be initiated.

3). The present methodology assumes that the entire mass behaves as if it is in the dissolved form. This conservative assumption may be sufficient for a preliminary evaluation. The more realistic condition of partitioning into the dissolved and particulate components should be used, however. Sufficient information and data are presently available with respect to partitioning coefficients, and could readily be used in both the existing modeling framework, as well as the recommended one.

4). The methodology for evaluating short-term impacts deals only with plumes from individual barges, and makes no attempt to address the problem of mass loading (see page 3-3). Calculating a meaningful dilution factor for individual barges for the 106-Mile site also presents a number of problems. As pointed out in section 2.1.1, dispersion in the upper water column is highly variable. This variability is poorly understood and could substantially affect calculations of an appropriate dilution factor and subsequent estimates of exposure and toxicity.

5). It is difficult to accept the assumption of no settling of the sludge particles. The experimental data, on which the assumption was originally based, are for the digested sludges of the Los Angeles County Sanitation District, sludges that are known to settle poorly in the sludge digestor. Other, more recent measurements made on sludges from New York City treatment plants have serious experimental inconsistencies. Due to its probable significance, the issue should receive further consideration. At this time, an alternative examination of environmental effects when settling is included in the analysis, should be performed.

b. Potential for Toxicity to Aquatic Life

Exposure pathway 1 examines the potential impact of sludge contaminants on aquatic organisms (Section 4.1). Sludge criteria are calculated for each potential contaminant in the sludge. These sludge criteria are in turn derived from ambient water quality criteria (AWQC) after correcting for an "appropriate dilution factor." This approach is consistent with EPA's use of AWQC for the regulation of point-source discharges. The specific approach presented in this document, however, suffers from a number of limitations which should be addressed.

1). The approach focuses exclusively on the impact of sludges on pelagic organisms. The assumption is made that no significant accumulation of particulates on the ocean bottom will occur for decades (see p. 3.2); however, assumptions regarding no settling of sludge related particles may not be valid. Thus it is inappropriate to ignore the potential impact of sludge on the benthos. This issue is addressed under future research needs of the methodology document. Without knowing the degree to which settled sludge contributes to the total impact, it is difficult to make a precise comparison of this approach to other sludge disposal options.

2). Another problem deals with the use of the AWQC to determine potential toxicity of sludge at the 106-mile site. The discussion of the AWQC (section 4.1.3.2.) is somewhat ambiguous, particularly relating to the use of chronic vs. acute criteria (both are apparently to be applied) and the particular version of the chronic criteria (Final Chronic Value, FCV vs. Final Plant Value, FPV vs. Final Residue Value, FRV). Moreover, AWQC for salt water organisms are only available for a limited number of contaminants and are most often based on organisms which are not indigenous to the site in question. Finally, AWQC deal only with individual contaminants, and may not provide an accurate estimate of the toxicity of a complex mixture. Although consistent with other EPA procedures, the use of AWQC may not be the most appropriate method of estimating sludge toxicity. These problems can be dealt with by using a site-specific approach to developing criteria for the 106-Mile site and/or making use of water column and suspended particulate bioassays.

In summary, each of the above limitations add a degree of uncertainty to the predictions generated by these models. Sensitivity analyses do not include these issues in estimates of the total error inherent in the combined calculations of a sludge criterion. Without these factors included in estimates of error, comparisons of the utility of ocean disposal of sludge with other options is difficult.

3). Another issue which was not considered in the risk assessment methodology is the effects of sludge nutrients on phytoplankton populations in the vicinity of the disposal site. Changes in the number and types of phytoplankton can not only modify the total biological community, but may change the compartmentalization and transport of contaminants. While this may not turn out to be a major issue, initial estimates of impact should be made for an appropriate range of dilutions (e.g. 1/5,000-1/500,000). If any sign of impact is found, then this problem should be addressed in a more detailed fashion to determine its potential for impact at the population and community level. If no impact is observed in the initial evaluation there may be no need to go further. If it is impossible to estimate impacts from current data, then the data gaps should be addressed and dealt with so that preliminary estimates of impact can be made. Finally, with the uncertainties associated with the above predictions, the ongoing monitoring program should include a component which addresses the potential impact of nutrients on phytoplankton.

c. Impacts on Human Health

The major issues in Section 3.2 deal with exposure to aquatic organisms, bioconcentration factors of contaminants for exposed organisms, and dietary intake of contaminated organisms by humans. The calculations of transport and fate of contaminants, which provides a basis for estimating exposure, are dealt with in earlier sections of this report. These calculations use bioconcentration factors (BCFs) for estimating human exposure potential.

1). In general the discussion of bioconcentration factors (BCFs) is well done. Several approaches for deriving BCFs are reviewed including physical/chemical (e.g., octanol-water partition coefficents, K_{OW}) and empirical biological studies. The document uses a geometric mean of available biological data to calculate a final BCF. This is consistent with the approach taken with the AWQC and appears to be as appropriate as any approach available today. BCFs, however, are quite variable, and for chlordane a range of reported BCFs of 4 orders of magnitude are used to calculate a geometric mean BCF. Appropriately the effects of this variability on the SC are examined in the sensitivity analysis section and are found to be significant. No BCFs are available for the species of interest at the 106-Mile dump site. Because of the variability in BCFs the document recommends that specific BCF values be generated for organisms of concern in the dump site area. While this may not be possible for all of the species present at the site (e.g. swordfish), it may provide a better estimate of the potential BCFs and thus a more realistic estimate of exposure potential for humans.

2). A point that is not dealt with in the methodology is the potential for contaminant biomagnification. The use of BCFs is limited to the direct accumulation of contaminants from the water column and does not deal with potential magnification through the food chain. This potential should also be evaluated and, if found significant, should be included in the final methodology.

d. Miscellaneous

1). pg 3.3 and 4.3 - The document should include a list of the AWQC that are available so that the users of the methodology and any reviewers can ascertain whether adequate criteria are available for use in the methodology.

2). pg 3.3 (bottom) and 3.4 (top) - Human contact by bathers at the nearest beaches is considered to be trivial and is not considered an important risk pathway needing attention. This may be true, but the methodology provides no logic to justify such an assumption. Therefore this assumption appears to be made in an arbitrary and capricious manner. Any assumptions presented without reasonable logic to justify them reduce the overall credibility of the document.

3). Figure 4.1 - On this and related figures, the dilution factors are stated in a legend. However, there is no information to indicate which factor is related to which contour. More explicit designation should be made on such figures to avoid confusion and error.

4). Table 4-13 - On page 4-2, a consumption value of 52.7 grams/day is stated as the value that should be used in the methodology. Based on the data in Table 4-13 this seems to be protective of all individuals except those over 50 and orientals. More detailed information is needed to justify the consumption value of 52.7 grams/day and to maintain the credibility of this part of the methodology.

5). pg 4-48 - The last sentence in the section on human body weight indicates that values for toddlers or infants should be used where children are known to be a special risk. While the statement sounds reasonable, it is inconsistent with previous sections in which the fish consumption of an over 50 oriental or consumption at the 95 percentile (52.7 grams/day) are assumed. Clearly the human body weight used should be that representative of the fish consumption rate that is used or assumed. One doubts that toddlers or infants consume 52.7 grams/day of fish. The discussion of human body weight should be rewritten to be more consistent with other assumptions in the document.

APPENDIX A

U.S. ENVIRONMENTAL PROTECTION AGENCY
ENVIRONMENTAL ENGINEERING COMMITTEE
SCIENCE ADVISORY BOARD

COMMITTEE TO REVIEW REGULATIONS ON OCEAN DUMPING AND REUSE AND DISPOSAL OF SEWAGE SLUDGE

	Membership on Subgroup(s)
Dr. Raymond C. Loehr (Chairman) Civil Engineering Department University of Texas Austin, TX 78712	Landfilling
Dr. Larry W. Canter * Professor of Civil Engineering and Environmental Science University of Oklahoma 200 Felgar Street, Room 127 Norman, OK 73019	Overall Risk Assessment Land Application
Mr. Richard A. Conway Corporate Development Fellow Union Carbide Corporation P. O. Box 8361 (770/342) South Charleston, WV 25303	Incineration
Mr. Allen Cywin ** Consultant 1126 Arcturus Lane Alexandria, VA 22308	Incineration
Dr. Benjamin C. Dysart, III Environmental Systems Engineering Department Clemson University Clemson, SC 29634-0919	Overall Risk Assessment
Dr. Ben Ewing Professor of Environmental Studies Institute for Environmental Studies University of Illinois 408 S. Goodwin Urbana, IL 61801	Landfilling (Chair)
Dr. Davis L. Ford Davis L. Ford and Associates 2901 N. Interregional Austin, TX 78722	Ocean Disposal

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Notes:

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Dr. Rolf Hartung *** School of Public Health University of Michigan Ann Arbor, MI 48109	Overall Risk Assessment
Dr. J. William Haun 13911 Ridgedale Drive Suite 343 Minnetonka, MN 55343	Landfilling
Dr. George M. Hidy President Desert Research Institute P.O. Box 60220 Reno, NV 89506	Incineration
Dr. Robert Huggett *** College of William and Mary Chairman, Department of Chemical Oceanography Virginia Institute of Marine Sciences Gloucester Point, VA 23062	Dredged Material (Chair)
Dr. Kenneth D. Jenkins *** Professor of Biology California State University at Long Beach Long Beach, CA 90840	Dredged Material Ocean Disposal
Dr. Joseph T. Ling 3M Company 3M Community Service Executive Program Building 521-11-01 St. Paul, MN 55144	Landfilling
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Dr. Charles R. O'Melia Professor of Environmental Engineering Department of Geography and Environmental Engineering The Johns Hopkins University Baltimore, MD 21218	Dredged Material Ocean Disposal
Dr. Albert Page ** Department of Soil & Environmental Sciences University of California Riverside, CA 92521	Land Application (Chair)
Dr. Mitchell Small Department of Civil Engineering Carnegie-Mellon University Schenley Park Pittsburgh, PA 15213	Landfilling Land Application
Dr. Evan Vlachos * Colorado State University Department of Sociology Fort Collins, CO 80523	Overall Risk Assessment (Chair)
Dr. Bernard Weiss **** Division of Toxicology University of Rochester School of Medicine Rochester, NY 14642	Overall Risk Assessment

Executive Secretary

Mr. Harry C. Torno (until 9/86)
Executive Secretary, EEC
Science Advisory Board (A-101F)
U.S. Environmental Protection Agency
Washington, D.C. 20460

Mr. Eric Males (after 9/86)
Executive Secretary, EEC
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APPENDIX B

Environmental Engineering Committee
Science Advisory Board
U.S. Environmental Protection Agency

REVIEW OF TECHNICAL MATERIAL SUPPORTING REVISIONS TO SLUDGE DISPOSAL/REUSE REGULATIONS

Charge to the Committee

To review and advise OWRS on chemical-by-chemical methodologies for various disposal options, including:

A. Their scientific validity.

B. Their consistency of approach and assumptions, both within each methodology, and among the various methodologies.

C. The identification of modeling and data needs.

APPENDIX C

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 17, 1986

MEMORANDUM

SUBJECT: Summary of Al Rubin's Response to 10/6 Memo on Purpose of Sludge Risk Assessments

FROM: Eric Males EM

TO: EEC (Sludge Subcommittee)

As I mentioned to you in my last memo, Al Rubin suggested responding orally to the 10/6 memo at the October 9 meeting in Cincinnati. This memo summarizes for you his comments.

1. The initial purpose of the methodologies is to evaluate the MEU risks of sludge management practices to support the calculation of national criteria. These criteria are typically expected to be numeric constituent concentrations which may differ by practice. The national criteria will be single numbers, assuming "reasonable worst case" conditions and "typical" engineering practices. Such practices may also become part of the national criteria. In essence, these criteria are expected to make each practice (under "reasonable worst case" conditions) equally risky (to MEUs).

EPA, however, also expects to apply these methods to individual sites, using site-specific data. Such calculations will produce site-specific criteria that may differ from the national criteria.

2. The purpose of documents under review is to communicate the methodologies and assumptions to EPA (the initial users) and to commenters on the proposed national criteria. EPA will be the only user of the methodologies, initially. Eventually, however, state and local decisionmakers, as well as regulated facilities, will conduct site-specific runs. EPA expects to develop a user manual document to assist future users, particularly Federal and State permit writers.

3. Thus, the assessments are expected to eventually support several levels of decisions, namely, establishing national criteria and developing more local or site-specific criteria.

4. The methodologies provide the tool to, in essence, backcalculate the criteria. Clearly, facilities will also use other factors to make their sludge management decisions.

5. Al Rubin's office, the Wastewater Solids Criteria Branch within the Office of Water Regulations and Standards, will make decisions on the national criteria, subject to Agency review and public comments.

cc: Terry Yosie, SAB
Al Rubin, CWRS
Larry Fradkin, ECAO

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OCT 2 1986

MEMORANDUM

OFFICE OF
THE ADMINISTRATOR

SUBJECT: Clarification of Purpose of Sludge Risk Assessments

FROM: Eric Males, Executive Secretary EEC
Science Advisory Board (A-101F)

THRU: Terry Yosie, Director
Science Advisory Board (A-101)

TO: Alan Rubin, Chief
Waste Water Solids Criteria Branch
Office of Water Regulations and Standards (WH-585)

As you know, the Environmental Engineering Committee of the Science Advisory Board is in the midst of reviewing the risk assessment methodologies for sludge management prepared by ORD/ECAO for your office. Before completing its review, the committee needs you to clarify the intended purpose and applications of these assessments. Please briefly respond to the following questions.

1. What is the intended purpose of these assessments?
2. Who is the intended audience for these documents? Who are the intended users of these methodologies?
3. What decisions will these assessments support (e.g., establishing national criteria, making local sludge management decisions)?
4. How will information from these assessments be a part of those decisions?
5. Who will make those decisions?

Please respond to these questions within the next two weeks. If possible, we would appreciate your response by COB Wednesday October 8. Please call if you have any questions (382-2552).

cc: Ray Loehr, Chmn. EEC
Larry Fradkin, ECAO

EXAMPLE COMPARISON MATRIX OF ASSUMPTIONS AND METHODS

This appendix has been prepared to illustrate how a review of the consistency of the methodologies across the four disposal options could be structured. The basic component of the review could be a comparison matrix as shown in the example, Diagram D-1. The disposal options appear as columns. Methodological elements (or dimensions) appear as rows. (Diagram D-2 shows the relationships of these elements or dimensions, as understood by the Committee.) The cells within the example matrix are coded according to the letters that appear in this second diagram. The numbers in the matrix correspond to disposal options. Examples of key highlights of information are displayed in bullet format, following the diagrams. This information should be expanded and refined by EPA in conjunction with the preparation of the recommended synthesis document.

The example matrix also contains a column identifying common considerations across the four disposal options, and a row identifying data needs and uncertainties in the methodologies. Information on these cells also appears in the bulletted text following the diagrams.

Finally, it is stressed that the comparison matrix in Diagram D-1 is only an example. It needs to be completed and improved by EPA as part of the proposed synthesis document.

Diagram D-1: Comparison Matrix

Disposal Options (Practices)

Items or Dimensions	Ocean 1	Land-fill 2	Inciner-ation 3	Land Appli-cation 4	Overarching Considerations 5
Source (A)	A1	A2	A3	A4	A5
Pathways (B)	B1	B2	B3	B4	B5
Receptors (C)	C1	C2	C3	C4	C5
Exposure (D) (Models) (Receptors)	D1	D2	D3	D4	D5
Criteria (E)	E1	E2	E3	E4	E5
Scientific Revision of Management Practice (Source) (F)	F1	F2	F3	F4	F5
Data/Uncertainty (X)	X1	X2	X3	X4	X5

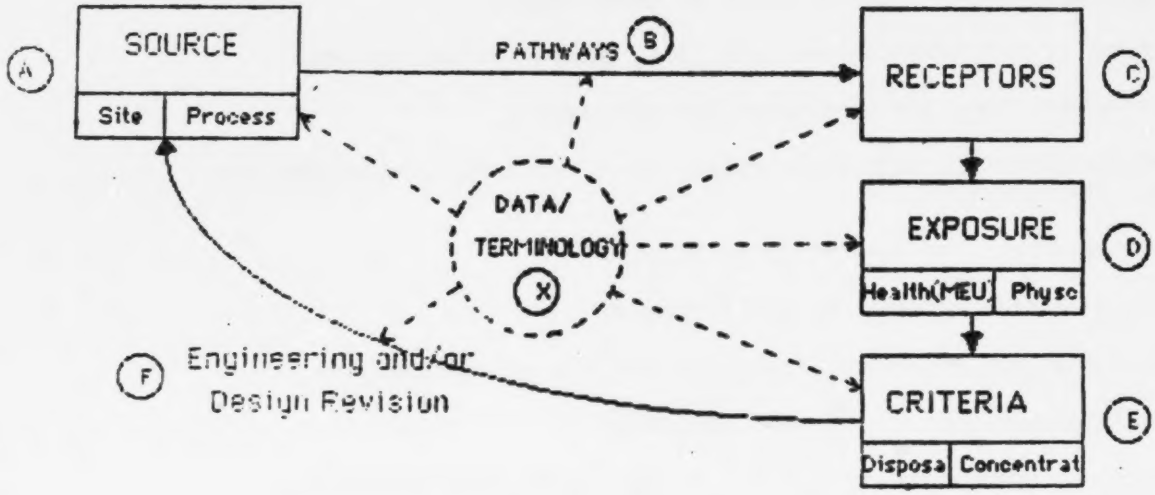
SOURCE
Site
Process
A
PATHWAYS
B
RECEPTORS
C
DATA/
TERMINOLOGY
X
EXPOSURE
Health(MEU)
Physc
D
CRITERIA
Disposa
Concentrat
E
F
Engineering and/or
Design Revision

Diagram D-2: Flowchart for Criteria Derivation Within Each Disposal Option

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A1 - well-characterized and specific on barges, barge sizes, etc.

- transport to site and transportation accidents not considered
- "loading" not addressed (frequency and rate of application)
- release of constituents within water column is assumed

A2 - unlined landfill is assumed

- transport to landfill not considered
- well-characterized by data on current practices
- applicability of TCLP to sludge is questionable

A3 - there is lack of emissions data (D2), except for particulates

- transport risks not considered for all options
- start-up and unsteady state operation of incinerator emissions are not characterized
- wet scrubbers are assumed to be in place
- residual side streams are not addressed

A4 - "loading" not addressed (frequency and rate of application)

- questionable approach on vapor emissions
- there is tremendous variability of land application practices, application rates, and sludge types (wet or dry)
- transport to site not considered

A5 - many organic compounds are not measured or referred to; in addition, the metabolites or incomplete combustion products of many organics are either not known or not referred to

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B1 - sludge deposition not considered

B2 - no consideration of ground water to surface water pathway and subsequent or other implications for wildlife and food chain

- direct ingestion of ground water addressed
- vapor pathway also considered in adequate manner

B3 - inhalation pathways considered only with respect to particulates

- no deposition pathways considered
- need to consider residuals pathways (e.g., ash to landfilling), assumes with scrubber water recycled into headend of POTW

B3 - need for ash leachate testing (TCIP?)

B4 - 13 pathways described (most comprehensive)

B5 - need systematic approach for identifying and selecting/eliminating pathways based on quantitative approach

---

C1 - no benthos identified

- pelagic and humans identified (human fish eater)

C2 - human receptors used (breathe and drink)

- no ecosystem MEUs

- focus on humans living in proximity

- person drinks 2 l per day for lifetime

C3 - human receptors used (breathe)

- no secondary (indirect) human exposure

- no ecosystem (MEUs)

- person breathes 20 m^3/day every day of his/her 70 year life

C4 - human receptors used (eating food and dirt)

- human (breathing) -- sludge applicator as a receptor

- human receptors used (drinking water)

- MEUs (plants, biota, etc.) considered

C5 - need to use concept of Most Exposed Unit (MEU) rather than MEI

- ecosystemic effects are inconsistently considered

- need to consider pattern of risk distribution

D1 - simple mixing model used for calculating concentration to aquatic life in 4 hr period -- this is more empirically based and adequate

- long-term dilution control models (using state-of-art for applied ocean dilution models); assumes total conservation on chemicals; need to have particulate and dissolved phase not just all dissolved phase

- unknowns exist on bio-availability of chemicals due to changes in saline environment

D2 - nitrogen kinetics may not be appropriate

D2 - models are satisfactory for applied state-of-art

- anaerobic vs aerobic conditions effects on chemistry/transport are of concern, different rates for anaerobic conditions (data weakness exists)
- equilibrium vs nonequilibrium models
- complex hydrogeology makes site specific application difficult
- degradation of vapors needs to be in vapor model (data weakness exists)

D3 - lack of source term data

- models are satisfactory for applied state-of-art
- easier to use on site specific conditions
- rough terrain not considered

D4 - similar comments to landfill on ground water and vapor models (D2)

- USLE and MUSLE used -- may have better models for runoff
- plants and crop uptake models are empirical (these are state-of-art on metals uptake)

D5 - have selected transport and fate models been validated for site specific usage? Relative to health effects and nonhealth effects, need to: a) consider mixtures of chemicals; b) point out lack of data on phytotoxicity and effects on wildlife

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D1-4 - health effects and nonhealth effects -- the human and nonhuman toxicity effects data appear to be consistent and standard; however, the general debate on certain basic assumptions is still ongoing

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E1 - effects on aquatic life (short term) -- criteria based on disposal of sludge with concentration of constituents which will meet 4 hr water quality criteria

- effects on humans -- expressed on mass/day for each contaminant for whole site (loading rate)

E2 - criteria primarily based on TCLP and in form of leachate concentration (see above Source comments on TCLP) -- might want to address whole concept of using an extraction procedure

E3 - limited criteria based on allowable limiting concentrations in input sludge based on worst case dispersion

E4 - application rate (kg/ha) for chemicals

- concentrations in sludge used as output

F5 - this is based on determining the assimilative capacity of the environmental system; this can be a very difficult task

---

F1 - change rate of discharge for short term (this is a change of a management practice)

- decrease mass/day

- have pretreatment for toxics

- siting decisions can be based on approach

F2 - methodology does not include evaluation of liners

- have pretreatment for toxics

- siting decisions can be based on approach

F3 - air pollution control devices could be considered (afterburner)

- decrease feed rate to incinerator

- have pretreatment for toxics

- siting decisions can be based on approach

- increased stack height should be considered

F4 - have pretreatment for toxics

- siting decisions can be based on approach (minimum requirements on slope and hydrogeology)

- decrease loading rate and place over wider area

- impose waiting periods

- control soil pH

- incorporate into soil

- restrict public access

F5 - need to be sure the methodologies can incorporate the evaluation of the "range of management practices" in current existence; need to consider both structural and non-structural alternatives

---

X1 - release of chemicals (i.e., bio-availability)

X2 - rate constants

X3 - lack of emissions data

X4 - ecosystemic linkages

X5 - there is a need for sensitivity analysis

SENSITIVITY ANALYSIS OF CROP UPTAKE MODEL USED IN LAND APPLICATION METHODOLOGY

The Agency, in Chapter Four of the risk assessment document, has developed a mathematical model which will be used to select regulatory limits designed to protect the human diet against adverse increases in metal intake. The mathematical model is complex but basically attempts to predict what impact crops grown on lands where POTW sludge has been applied will have on the daily dietary metal intake of humans.

The mathematical model is composed of several theoretical aspects which are as follows:

1. As sludge is applied to a soil, trace element adsorption sites on the soil progressively become saturated so that the equilibrium concentration approaches that of the sludge. Additional sludge application will result in little, if any, increase in equilibrium concentration.

2. If the equilibrium concentration due to sludge application is less than that which will result in "excessive" concentrations in plant tissue (or damage to the plant itself), there is no need to limit the sludge application rate based upon the quantity of metal added to soil from sludge.

3. If the equilibrium metal concentration, due to sludge application, is high enough to cause "excessive" concentrations in plant tissue (or plant damage), limiting the sludge application rate will be required.

4. Plant availability of sludge-borne metals does not increase (stays the same or decreases) with time following termination of sludge application.

In developing the mathematical model, the document correctly dismisses concepts previously proposed which are no longer valid. These are:

1. The use of sludges spiked with metal salts is not representative of municipal sludges, and data from studies using such spiked sludges should not be used for regulatory purposes.

2. Greenhouse or pot studies are not indicative of plant metal uptake in the field and over predict uptake under field conditions.

3. Food consumption by the teenage male is not representative of the United States population.

4. The use of scenarios where sludge-amended crops make up the entire diet of an individual is not realistic.

5. Soil cation exchange capacity (CEC) is not a basis for determining regulatory metal application limits.

6. Crop response during the first year of sludge application is higher than that observed if applications are repeated annually.

The Agency is to be commended for having taken a great leap forward in the development of the mathematical model contained in Chapter Four which correctly utilizes the latest scientific principles and does not include the discarded theories of the past. However, there are several important aspects of the mathematical model which are open to question:

1. It remains to be seen whether sufficient data exist in the scientific literature to determine meaningful plateau values for a wide variety of crop types upon which valid regulatory limits can be based.

2. Although it may be theoretically possible, with the use of relative uptake values, to develop a regulatory limit using data from a single crop species, this procedure appears questionable at best.

3. It is not clear how sensitive the mathematical model shown in Chapter Four is to small changes in variables.

Because of the above noted problems with the mathematical model shown in Chapter Four of the risk assessment document, it was deemed necessary by the SAB to conduct computer runs using this model. These computer runs were needed to help the SAB determine the sensitivity and validity of the model and also help determine whether sufficient data are available to use it for regulatory purposes.

It should be noted that the Agency was requested to assist the SAB in the conduct of these computer runs but declined our request.

Table E-1 contains values of RP (lifetime Cd loading to soil in kg/ha) for various values of RIA (daily allowable Cd dietary intake in µg/day from crops groups on sludge treated soils) and FC (fraction of diet from crops grown on sludge treated soils). For informational purposes, values of RTC (reference tissue concentration in µg Cd/g) are also given. Where the table indicates that FC values are those of the EPA, this means that the FC values are from the various food groups as shown in Table 4-12 (page 4-62) of the risk assessment document.

Except for the indicated values for RIA and FC, the values for RP in Table E-1 were derived using the data contained in the example calculation contained in Section 4.8 (pages 4-90 to 4-109). Basically, this example calculation used the following input data:

1. Metal uptake by vegetables as found by R. H. Dowdy and W. E. Larson, "The Availability of Sludge-Borne Metals to Various Vegetable Crops," Journal of Environmental Quality, 4, 278-282, 1975.

2. Consumption by a 25 to 30 year old male (as found in Appendix 1 and Table 4-2 of the risk assessment document).

It should be noted that the example calculation in Section 4.8 does not include subtraction of TBI (total background intake from non-sludge applied foodstuffs) from RfD (risk reference dose). This step of the calculation was inadvertently omitted from the risk assessment document, but was subsequently pointed out by Mr. Randy Bruins of EPA in a discussion in August.

TABLE E-1

EFFECT OF VARYING PARAMETERS IN THE U.S. ENVIRONMENTAL PROTECTION AGENCY (EPA) RISK ASSESSMENT METHODOLOGY FOR LAND APPLICATION OF SLUDGE SHOWN IN CHAPTER FOUR

Model Parameters			
Increased Allowable Daily Intake of Cadmium (µg/day) (RIA)	Fraction of Diet (FC)	Reference Tissue Concentration of Cadmium (µg/g) (RTC)	Maximum Loading of Cadmium (kg/ha) (RP)
30	EPA*	9.27	15.3
60	EPA	17.9	29.6
90	EPA	26.6	44.0
	0.1	44.0	72.7
	0.2	38.8	64.1
	0.3	34.8	57.5
	0.4	31.5	52.1
120	EPA	35.2	58.2
240	EPA	69.9	116
360	EPA	104.5	173

*Values from Table 4-12 of EPA Risk Assessment Document

Rufus Chaney and James Ryan, in their paper "Basis For Risk Reference Dose For Dietary Cadmium Intake" (page 4), quote that average food intake of Cd in the USA is 38 µg/day and water contributes 4 µg/day. Thus, in the computer runs shown in Table E-1, a background daily cadmium input of 42 µg Cd/day was subtracted from all RfD values.

It can be seen that for all other variables being constant, changing the RIA from 30 to 360 µg/day (using the same FC values in Table 4-12) results in an eleven-fold increase in the allowable sludge loading rate. Thus, the sludge loading rate is directly influenced by the RIA values in a one to one ratio. Alternatively, for all other variables being constant, decreasing the FC value from 0.4 to 0.1 results in a 40 percent increase in allowable sludge application rate. It becomes obvious that the model will be extremely sensitive to changes in the values of FC and RfD. More directly, the selection of a regulatory limit for sludge application will, in large measure, depend upon the values of RfD and FC ultimately selected by the EPA.

The success of the mathematical model in Chapter Four depends upon the ability of the EPA to find sufficient data to select valid plateau values. A research study must include sufficient sludge loading rates so that a plateau value can be found.

The scientific literature was searched and as was suspected, many studies include only two sludge application rates and most do not last for more than two or three years. In addition, few studies include the growing of more than one crop type on the same soil, thus, not allowing the direct measurement of a relative uptake value.

Table E-2 contains plateau values pertaining to ten crops and the associated RTC values computed from equation given in the risk assessment methodology document (4-21). The data are collected from six studies conducted by five investigators. In verbal discussions with EPA (Mr. Randy Bruins), these studies include data which may be used by EPA for selecting regulatory limits.

The plateau values were obtained by examining the adequacy of fit of seven nonlinear models which are frequently employed in growth studies. Appendix E-1 contains the various models considered and the criteria used for examining the adequacy of fit of a model to the data. From Tables A1 and A2 of the appendix, it can be seen that the logistic model

$$Y = \frac{\alpha}{1 + \exp(\beta - \gamma x)}$$

stands out as the curvilinear model that fits most adequately to each of the ten data sets. Therefore, the estimate of the parameter is used as the plateau value in Table E-2.

Table E-2 summarizes the pertinent model parameters determined for each study. The RTC values shown are for the indicated crop studied in each experiment. Lettuce from the Dowdy and Larson (1975) study was used as the index crop in each case, and the RTC for each indicated crop was calculated using equation 4-21 from the risk assessment document. In all cases, an RIA of 22 µg Cd/day was used, assuming an RfD of 64 µg Cd/day and TBI of 42 µg Cd/day.

TABLE E-2

SLUDGE CONCENTRATION (SC), PLATEAU VALUE (P) AND REFERENCE TISSUE CONCENTRATION (RTC) USING THE MATHEMATICAL MODEL SHOWN IN THE LAND APPLICATION RISK ASSESSMENT DOCUMENT IN CHAPTER FOUR

Reference *	Soil pH	Maximum Cd Loading (Cumulative) (kg/ha)	Sludge Concentration (mg Cd/dry kg)	Plateau Value (P) (µg Cd/g)	Reference Tissue Concentration (RTC) (µg Cd/g)	Crop
1. Webber and Beauchamp	7.6	19.2	192	0.11	0.21	Corn grain
2. MSDCC	7.8	207	240	1.00	1.81	Corn grain
3. Hinesly	5.9-7.1	191	249	0.88	2.35	Corn grain
4. Chang and Page, 1985	7.1	80	44	12.1	20.1	Swiss chard
5. Chang and Page, 1985	7.1	80	44	2.46	4.45	Radish tuber
6. MSDCC	6.8-7.5	72	240	2.99	6.87	Tomato
	6.8-7.5	72	240	0.46	0.69	Green bean
	6.8-7.5	72	240	1.43	4.06	Carrot
	6.8-7.5	72	240	2.70	6.90	Beet
	6.8-7.5	72	240	25.1	43.0	Swiss Chard

*References given in Table E-3.

**Calculated using equation 4-18, and lettuce as index crop.

THE METROPOLITAN SANITARY DISTRICT OF GREATER CHICAGO

TABLE E-3

COMPLETE REFERENCES FOR STUDIES SHOWN IN TABLE E-2

Reference Number	Complete Reference
1	Webber, L. R., and E. G. Beauchamp. 1979. Cadmium concentration and distribution in corn (Zea Mays L.) grown on a calcareous soil for three years after three annual sludge applications. J. Environ. Sci. Health, B14(5): 459-474.
2	Metropolitan Sanitary District of Greater Chicago (MSDGC), Research and Development Department, Corn Grown at the Fulton County Land Reclamation Site Using Sludge as Fertilizer, 1973 through 1983.
3	Hinesly, T. D., University of Illinois, Department of Agronomy, Corn Grown on Blount Silt Loam Using Sludge as Fertilizer, 1970 through 1981.
4	Chang, A. C. and A. L. Page. 1985. University of California at Riverside, Vegetables Grown on Ramona Sandy Loam Using Sludge as Fertilizer, 1976 through 1985.
5	Ibid.
6	Metropolitan Sanitary District of Greater Chicago, Research and Development Department, Vegetables Grown in Urban Soil Using Sludge as Fertilizer, 1977 through 1979.

The data from the example calculation on page 4-92 of the risk assessment document was used to determine the sum of RU + DC + FC. In the case of wheat and corn grain which is not included in this example calculation, DC values were obtained from Table 4-2 of the risk assessment document for 25-30 year old males, and FC values of 0.1 were assumed. Varying FC for corn grain and wheat from 0.1 to 0.6, the highest value used in the risk assessment document example, does not substantially change the total RU + DC + FC sum.

One critical value in the calculations is the RU factor. In the studies presented in Table E-2, RU was calculated using equation 4-18, of the risk assessment document, the alternative procedure to equation 4-17 of the document, which uses linear response slopes to determine RU. Equation 4-18 is used when the index crop and other crop are grown on two different soils. Equation 4-18 is recommended when the slope of the linear equation cannot be calculated. If the slopes can be calculated from the data, then use of equation 4-17 is recommended. The formulas are valid only if they yield equivalent results when employed on the same data sets. Equation 4-18, as given, does not take into consideration the contaminant loadings in the two experiments. When this deficiency is accounted for, equation 4-18 yields results similar to equation 4-17.

A revised formula for equation 4-18 could correct the deficiencies in the existing formula. Let A_1 and A_2 denote the uptake by crop A corresponding to a contaminant loading of x_1 and x_2, respectively, in one experiment. Similarly, let I_1 and I_2 denote the uptake by the index crop due to a corresponding contaminant loading of y_1 and y_2, respectively, in another experiment. Then the relative uptake is calculated as follows:

$$RU_{A1} = \frac{(A_2 - A_1)}{(x_2 - x_1)} \div \frac{(I_2 - I_1)}{(y_2 - y_1)}$$

$$= \frac{(y_2 - y_1)}{(x_2 - x_1)} \times \frac{(A_2 - A_1)}{(I_2 - I_1)}$$

To illustrate the deficiency of equation 4-18, RU_{AI} values were computed using the Swiss chard data of Chang and Page (Experiment I), and lettuce data of Larson and Dowdy (Experiment II). Below are the relevant values for this computation.

Crop Type		Experiment I Swiss Chard	Experiment II Lettuce
Mean Tissue Concentration (Computed from treated plots)	(µg/g)	4.5532 (A_2)	1.89 (I_2)
Control Tissue Concentration	(µg/g)	0.6295 (A_1)	0.61 (I_1)
Linear Response Slope	(µg/g[kg/ha]$^{-1}$)	0.1821 (B_1)	0.605 (B_2)
Mean Cd Loading for Treated Plots	(kg/ha)	19.8861 (x_2)	1.94 (Y_2)
Mean Cd Loading for Control Plots	(kg/ha)	0.0 (x_1)	0.0 (Y_1)

Using Equation 4-17 (Using ratio of slopes)
$$RU_{AI} = \frac{0.1821}{0.605} = 0.3009$$

Using Equation 4-18
$$RU_{AI} = \frac{4.5532-0.6295}{1.89-0.61} = \frac{3.9237}{1.28} = 3.0653$$

RU_{AI} computed from equation 4-18 is ten times higher than that computed from equation 4-17. Such a discrepancy in RU_{AI} values vanish if we compare the increments in tissue concentration corresponding to the same sludge loading or unit sludge loading. That is, an increment of 3.9237 (µg/g) in Swiss chard was caused by an increased loading of 19.8861 kg/ha or 0.1973 (µg/g) per kg/ha of loading. A corresponding number for lettuce, employing a similar computation is 0.6597. Now,

$$RU_{AI} = \frac{0.1973}{0.6597} = 0.299$$

which is almost the same as that obtained using equation 4-17.

Without reference to P values, the relative magnitude of RTCs (after adjusting for background concentration) is proportional to the respective linear slopes. That is,

$$\frac{(RTC_I - BC_I)}{(RTC_s - BC_s)} = \frac{\beta_I}{\beta_s}$$

Thus, the linear slope β for each crop has to be estimated with high precision, as β's enter the computation of RTC via RU. If the uptake curve is indeed curvilinear, exhibiting a plateau, a linear fit to the data gives an imprecise β (with low R-square values), and such a fit will be inadequate. The RUs, which are expected to provide measures of equivalent tissue concentration of a crop in terms of index crop, either yield underestimates or overestimates but never unbiased estimates. In this case, RTC, in turn, will provide biased estimates for the true (unknown) reference tissue concentration.

One of the obvious conclusions that one reaches after using the mathematical model in Chapter Four is that the model results depend, in great part, upon the curve which is chosen for selecting a plateau value. Curve fitting by those who wish to obtain conservative regulatory limits may differ from those wishing to obtain more realistic ones.

In conclusion, this study has found that the mathematical model in Chapter Four of the EPA risk assessment methodology for Land Application and Distribution and Marketing of Municipal Sludge incorporates some valid scientific principles. The EPA is to be commended for discarding those past concepts which have been proven invalid. The model has been found to be quite sensitive to selection of values of RIA (daily allowable Cd dietary intake in ug/day from sludge-fertilized crops) and FC (fraction of diet from sludge-fertilized crops), and be greatly dependent upon the curve fit selected to obtain P (tissue concentration plateau) values. Thus, it is important that realistic, reasonable values for these parameters be used when the model is used for regulatory purposes.

APPENDIX E-1

ESTIMATION OF PLATEAU VALUES

The uptake (Y) of Cd by crops is assumed to attain a plateau for large cumulative Cd loadings (x) on soil. Several parametric functions can be considered to describe such a plateau effect. However, we consider only those models that have been employed, frequently, in fitting growth curves. Further, we assume that the plateau value is the value of the uptake, Y, when the loading x is very very large; that is, when x is infinity. For each model we consider here, such a plateau value is measured by a parameter α of the model, which is estimated from the data except in equation (3). In the case of equation (3), the plateau is measured by the ratio of two parameters β and γ of the model.

The first two models are characterized as sigmoidal growth curves and are often employed in growth studies:

Logistic model: $$Y = \frac{\alpha}{1+\exp(\beta-\gamma x)} + \varepsilon \qquad (1)$$

Gompertz model: $$Y = \alpha \exp(-\exp(\beta-\gamma x)) + \varepsilon \qquad (2)$$

The third one, Langmuir type model, is given by

$$Y = \frac{\alpha+\beta x}{1+\gamma x} + \varepsilon \qquad (3)$$

For this model, β/γ measures the plateau effect.

The fourth model describes Mitscherlich's law by

$$Y = \alpha - \beta\gamma^{x} + \varepsilon \qquad (4)$$

and has been frequently employed to study the effect of fertilizer on yield in agricultural experiments.

The fifth model is given by

$$Y = \alpha \exp(-\beta/(x+\gamma)) + \varepsilon \qquad (5)$$

and is often used in growth studies.

The sixth and seventh models are variations of the model (4) above, and are employed to study growth phenomenon.

$$Y = \alpha(1-\beta \exp(-\gamma x)) + \varepsilon \qquad (6)$$

$$Y = \alpha-\beta \exp(-\gamma x) + \varepsilon \qquad (7)$$

We included these two models in this study to exhibit the sensitivity of the parameters to nonlinear estimation.

All seven models are nonlinear regression models with additive error. The parameters are estimated by least squares criterion employing iterative methods. The seven models are fitted to each of the ten data sets. The estimates of the parameters α, β, and γ are given in Table A1. The mean residual sum of squares is given by $\bar{\sigma}^2$.

The goodness or adequacy of the fit of a linear regression is assessed, usually, by R-square. There is no corresponding measure of adequacy of fit in nonlinear regression. Such an assessment is carried out by examining four statistics: (1) the percent bias, (2) the intrinsic effect curvature (IN), (3) the parameter effect curvature (PE), and (4) the usual t-statistics. These quantities, for each fit of a model, are presented in Table A2. The t-statistic values are indicated in parenthesis. A good fit is the one for which: (1) the percent biases are small, (2) the curvature effects, IN and PE, are small, and (3) the t-values are large.

Using these criteria, we see that the logistic model provides the best fit to each of the data sets. Therefore, we use the computed values of α, from the logistic model, as the estimates of plateau for each data set. Such plateau values are compared to the RTC values in Table F-2.

From these data sets we find, using the criteria for selecting an appropriate nonlinear model, the logistic model best fits the data. This can be verified using the data from other studies. If the same conclusion holds, then it can be said that the plateau values can be best estimated by the parameter α of the logistic model. Such a result provides a standardization of estimation of plateau value.

The statistical theory of nonlinear regression estimation, the criteria of assessing the adequacy of a fit and the computer program written in FORTRAN to compute several of the quantities are given in a recently published book by Ratkowsky: Ratkowsky, David A. (1983), Nonlinear Regression Modelling - A Unified Practical Approach, Marcel Dekker, Inc., New York.

THE METROPOLITAN SANITARY DISTRICT OF GREATER CHICAGO

TABLE A1

LEAST SQUARES ESTIMATES OF PARAMETERS α, β, AND γ OF SEVEN MODEL FUNCTIONS AND RESIDUAL VARIANCE $\hat{\sigma}^2$.

Reference*	Crop	Number of Data Points	Parameters of Model**	Nonlinear Models with a Plateau Parameter**						
				1	2	3	4	5	6	7
Webber and Beauchamp	Corn	24	α	0.107	0.120	0,0257	0.189	0.033	0.189	0.189
			β	1,143	0.438	0.005	0.163	5.970	0.865	0.163
			γ	0.179	0,103	0.016	0.970	2.035	0.030	0.030
			$\hat{\sigma}^2$	0,0003	0.0003	0.0004	0.0003	0.0003	0.0004	0.0004
MSDGC	Corn	37	α	1.001	1.087	0.104	1.597	1.920	1.597	1.597
			β	1.838	0.790	0.008	1.493	153.265	0.935	1.493
			γ	0.029	0.017	0.003	0.995	53.423	0.005	0.005
			$\hat{\sigma}^2$	0.0059	0.0055	0.0057	0.0057	0.0056	0.0057	0.0057
Hinesly	Corn	45	α	0,879	0.934	0.239	1.078	1.413	1.078	1.078
			β	0.870	0.272	0,007	0.836	131.942	0.776	0.836
			γ	0,021	0.014	0,005	0.993	74.764	0.007	0.007
			$\hat{\sigma}^2$	0,0608	0.0607	0,0605	0.0605	0.0605	0.0633	0.0633
Chang and Page	Swiss Chard	99	α	12,081	13.953	0,545	29.053	23.708	29.053	29.053
			β	2,152	0.956	0,245	28.466	55.077	0.980	28.466
			γ	0,084	0.044	0,005	0.992	15.540	0.008	0,008
			$\hat{\sigma}^2$	5.537	5.202	4,836	4.847	4.928	4.847	4.847
Chang and Page	Radish Tuber	99	α	2.459	3.096	0.345	5.109	4.414	5.110	5.110
			β	1,492	0.661	0.056	4.734	48.561	0.927	4.734
			γ	0.075	0.035	0.009	0.990	19.172	0.010	0.010
			$\hat{\sigma}^2$	0.4083	0.3944	0,3765	0.3780	0.3807	0.3780	0.3780
MSDGC	Tomatoes	15	α	2.990	3.080	0.978	3.261	4.078	3,261	3.261
			β	0,629	0.102	0.108	2.270	25.873	0,696	2.270
			γ	0.072	0:051	0.026	0.968	18.189	0.032	0.032
			$\hat{\sigma}^2$	0,1174	0.0937	0,0917	0,0923	0.0919	0.0923	0.0923

Table continued on following page.

THE METROPOLITAN SANITARY DISTRICT OF GREATER CHICAGO

TABLE A1 (Continued)

LEAST SQUARES ESTIMATES OF PARAMETERS α, β, AND γ OF SEVEN MODEL FUNCTIONS AND RESIDUAL VARIANCE $\hat{\sigma}^2$.

Reference*	Crop	Number of Data Points	Parameters of Model**	Nonlinear Models with a Plateau Parameter**						
				1	2	3	4	5	6	7
MSDGC	Green beans	15	α	0.463	0.471	0.321	0.489	0.635	0.489	0.489
			β	0.342	-0.122	-0.0017	0.290	28.719	0.594	0.291
			γ	0.069	0.050	-0.051	0.967	25.034	0.033	0.033
			$\hat{\sigma}^2$	0.0090	0.0093	0.018	0.0096	0.0098	0.0096	0.0096
MSDGC	Carrots	15	α	1.427	1.442	1.211	0.951	***	0.951	0.951
			β	0.036	-0.324	-0.145	-0.063	***	-0.066	-0.063
			γ	0.206	0.159	-0.114	1.044	***	-0.043	-0.043
			$\hat{\sigma}^2$	0.2529	0.2519	0.3464	0.2081	***	0.2081	0.2081
MSDGC	Beets	15	α	2.695	2.807	0.441	3.161	3.853	3.160	3.160
			β	1.195	4.801	0.091	2.688	30.482	0.850	2.686
			γ	0.071	0.049	0.022	0.974	14.321	0.026	0.026
			$\hat{\sigma}^2$	0.1119	0.0979	0.797	0.0836	0.0826	0.0836	0.0836
MSDGC	Swiss chard	15	α	25.111	29.809	30.570	83.831	59.181	83.833	83.834
			β	1.166	0.746	0.291	80.748	11.845	0.963	80.751
			γ	0.045	0.025	0.002	0.997	40.911	0.004	0.003
			$\hat{\sigma}^2$	3.1053	2.7194	2.2494	2.2539	2.4725	2.2539	2.2539

* References given in Table E-3.

** Equations for seven models given in text of Appendix E-1.

*** Estimation process did not converge.

THE METROPOLITAN SANITARY DISTRICT OF GREATER CHICAGO

TABLE A2

BOX'S PERCENTAGE BIAS, t-STATISTICS AND INTRINSIC (IN) AND PARAMETER-EFFECTS (PE) CURVATURES FOR SEVEN MODELS

Reference*	Crop	Parameter**	Nonlinear Models with a Plateau Parameter** 1	2	3	4	5	6	7
Webber and Beauchamp	Corn	α	9.012(5.36)	22.521(3.08)	112.048(3.58)	200.030(0.87)	72.117(1.30)	200.048(0.87)	200.052(0.87)
		β	11.315(3.81)	27.117(2.30)	20.584(1.64)	231.478(0.76)	98.922(0.86)	13.173(6.13)	231.501(0.76)
		γ	3.997(2.51)	3.626(1.72)	48.209(0.48)	0.068(19.05)	55.770(1.10)	2.305(0.57)	2.305(0.57)
		IN	0.267	0.244	0.355	0.236	0.362	0.236	0.236
		PE	4.131	10.209	36.470	80.068	7.940	97.144	81.335
MSDGC	Corn	α	0.350(20.08)	0.756(14.68)	2.634(4.89)	6.733(4.67)	2.239(6.96)	6.733(4.67)	6.733(4.67)
		β	0.543(14.35)	0.700(13.41)	0.997(7.01)	7.216(4.48)	3.342(4.34)	0.296(65.61)	7.216(4.48)
		γ	0.639(9.74)	0.593(7.89)	3.141(2.44)	-0.003(593.42)	2.429(4.35)	0.598(3.01)	0.598(3.01)
		IN	0.058	0.103	0.124	0.086	0.123	0.086	0.086
		PE	0.590	1.151	1.221	8.469	0.845	8.837	8.492
Hinesly	Corn	α	9.513(4.67)	17.291(3.45)	22.132(3.3)	50.569(1.93)	39.657(1.83)	50.568(1.93)	50.568(1.93)
		β	16.634(2.46)	40.821(1.21)	22.571(1.48)	65.548(1.57)	86.308(0.88)	9.108(7.31)	65.546(1.57)
		γ	9.456(2.07)	9.275(1.60)	43.622(0.75)	-0.068(131.2)	53.191(1.06)	10.003(0.93)	10.003(0.93)
		IN	0.569	0.491	0.565	0.420	0.574	0.420	0.420
		PE	4.372	7.716	7.491	20.324	7.183	22.467	20.399
Chang and Page	Swiss chard	α	0.909(11.54)	2.207(8.01)	30.571(1.49)	40.114(1.76)	4.372(4.67)	40.115(1.76)	40.115(1.76)
		β	1.406(9.66)	1.614(10.23)	2.103(5.21)	40.966(1.75)	5.964(3.04)	0.545(82.18)	40.967(1.75)
		γ	1.861(6.23)	1.734(4.96)	8.622(1.32)	-0.014(167.29)	4.681(2.64)	1.991(1.36)	1.991(1.36)
		IN	0.265	0.193	0.200	0.139	0.194	0.139	0.139
		PE	0.958	1.992	3.850	31.281	1.056	32.100	31.414
Chang and Page	Radish Tuber	α	1.824(8.80)	6.603(4.93)	24.654(3.30)	56.518(1.55)	8.439(3.64)	56.529(1.55)	56.525(1.55)
		β	2.594(6.57)	4.58(6.09)	5.502(3.34)	61.062(1.46)	14.697(2.06)	1.914(22.32)	61.070(1.46)
		γ	3.299(4.30)	2.89(3.13)	13.499(1.24)	-0.034(112.14)	10.453(2.15)	3.919(1.09)	3.918(1.09)
		IN	0.381	0.268	0.297	0.207	0.302	0.207	0.207
		PE	1.481	4.16	6.935	32.242	1.953	36.137	32.407

Table continued on following page.

THE METROPOLITAN SANITARY DISTRICT OF GREATER CHICAGO

TABLE A2 (Continued)

BOX'S PERCENTAGE BIAS' t-STATISTICS AND INTRINSIC (IN) AND PARAMETER-EFFECTS (PE) CURVATURES FOR SEVEN MODELS

			Nonlinear Models with a Plateau Parameter**						
Reference*	Crop	Para-meter**	1	2	3	4	5	6	7
MSDGC	Tomatoes	α	1.419(11.83)	2.256(9.88)	0.978(29.73)	4.657(7.07)	5.732(5.17)	4.657(7.07)	4.657(7.07)
		β	4.902(2.95)	20.204(0.76)	0.108(14.21)	6.894(5.20)	20.487(1.76)	1.679(13.11)	6.894(5.20)
		γ	3.628(3.68)	3.447(3.17)	0.026(12.10)	-0.101(72.84)	14.383(1.95)	3.415(2.35)	3.415(2.35)
		IN	0.384	0.326	0.332	0.274	0.335	0.274	0.274
		PE	1.583	2.304	18.318	4.152	2.786	4.377	4.224
MSDGC	Green beans	α	6.225(6.01)	10.624(4.88)	19.904(8.05)	22.815(3.46)	44.766(1.74)	22.808(3.46)	22.811(3.46)
		β	37.238(0.80)	-87.093(-.40)	19.728(-5.97)	39.667(2.16)	175.615(0.60)	12.723(4.58)	39.660(2.16)
		γ	17.33(1.64)	18.584(1.34)	5.783(-15.10)	-0.650(28.86)	108.297(0.73)	21.279(0.96)	21.279(0.96)
		IN	0.843	0.761	4.225	0.690	0.848	0.690	0.690
		PE	3.616	5.484	10.242	9.747	11.831	10.384	9.922
MSDGC	Carrots	α	5.346(7.11)	5.921(6.66)	17.240(7.23)	-32.687(2.75)	***	-3.687(2.75)	-32.687(2.75)
		β	472.035(0.04)	-20.88(-.56)	19.142(-5.29)	443.868(-0.31)	***	598.057(-0.28)	443.871(-0.31)
		γ	82.485(0.89)	82.555(0.87)	5.079(-10.74)	1.376(23.20)	***	30.081(-0.99)	30.081(-0.99)
		IN	1.989	1.825	0.876	0.934	***	0.934	0.934
		PE	4.316	4.804	9.274	62.881	***	77.181	62.122
MSDGC	Beets	α	2.243(8.79)	3.090(7.75)	47.260(2.94)	7.067(5.16)	5.000(5.04)	7.066(5.16)	7.066(5.16)
		β	4.452(4.32)	5.647(3.28)	9.671(3.15)	8.451(4.68)	13.104(2.16)	1.120(19.15)	8.451(4.68)
		γ	4.305(3.48)	3.514(3.20)	9.308(1.83)	-0.060(89.23)	10.765(2.07)	2.560(2.31)	2.560(2.31)
		IN	0.386	0.303	0.285	0.227	0.293	0.227	0.227
		PE	1.740	2.431	13.975	5.346	1.643	5.506	5.420
MSDGC	Swiss chard	α	8.016(4.93)	14.251(3.31)	11.054(4.25)	327.790(0.59)	22.350(2.17)	327.810(0.59)	327.822(0.59)
		β	5.163(8.04)	6.564(6.53)	2.729(3.82)	340.323(0.57)	22.625(1.77)	2.550(16.76)	340.356(0.57)
		γ	3.767(3.99)	1.644(2.79)	22.255(0.53)	-0.005(147.18)	13.287(2.14)	2.060(0.51)	2.059(0.51)
		IN	0.242	0.177	0.210	0.141	0.220	0.141	0.141
		PE	4.579	9.653	4.257	235.206	3.050	285.716	235.644

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*References given in Table 3 of the body of the text.

**Equations for seven models given in text of Appendix A. Number in parenthesis is t-statistic.

***Estimation process did not converge.

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